UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

CLEVELAND BAKERS AND TEAMSTERS HEALTH AND WELFARE FUND and PIPE FITTERS LOCAL UNION NO. 120 INSURANCE FUND, Plaintiffs, vs. PURDUE PHARMA L.P., THE PURDUE FREDERICK COMPANY, PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PRODUCTS L.P., CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC. (F/K/A ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. AND JANSSEN PHARMACEUTICA), JOHNSON & JOHNSON, INSYS THERAPEUTICS, INC., MALLINCKRODT PLC, MALLINCKRODT PHARMACEUTICALS, AMERISOURCEBERGEN CORP., AMERISOURCEBERGEN DRUG CORP., MCKESSON CORPORATION, and CARDINAL HEALTH, INC., Defendants.	CASE NO. 1:18-cv-854 JUDGE

DEMAND FOR JURY TRIAL

COMPLAINT FOR VIOLATION OF RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT

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I. INTRODUCTION

1. Plaintiffs Cleveland Bakers and Teamsters Health and Welfare Fund ("Cleveland Bakers & Teamsters") and Pipe Fitters Local Union No. 120 Insurance Fund ("Pipe Fitters") (collectively, "Plaintiffs") allege the following based upon the investigation of Plaintiffs' counsel against the following Defendants: Purdue Pharma L.P., The Purdue Frederick Company, Purdue Pharmaceutical Products L.P., Purdue Products L.P., Cephalon, Inc., Teva Pharmaceutical Industries Ltd., Endo International plc, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica), Johnson & Johnson, Insys Therapeutics, Inc., Mallinckrodt plc, Mallinckrodt Pharmaceuticals, AmerisourceBergen Corp., AmerisourceBergen Drug Corp., McKesson Corporation and Cardinal Health, Inc.

2. In 2014, more than 47,000 people died in the United States from lethal drug overdoses. In 2015, that number exceeded 52,000 and in 2016, it exceeded 64,000 – more than the number of U.S. soldiers who died during the entirety of the Vietnam War. [1] Sadly, this trend shows no sign of slowing. [2] More than three out of five of those deaths involve opioids – a dangerous, highly addictive and often lethal class of natural, synthetic and semi-synthetic painkillers.[3] These prescription opioids include brand-name medications like OxyContin, Opana, Subsys, Fentora and Duragesic, as well as generics like oxycodone, methadone and fentanyl. In all, more than 183,000 people died in the United States between 1999 and 2015 from overdoses directly related to

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[1] *Overdose Death Rates*, National Institute on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (last visited Mar. 28, 2018); *Vietnam War U.S. Military Fatal Casualties Statistics*, National Archives, https://www.archives.gov/research/military/vietnam-war/casualty-statistics.html (last visited Mar. 28, 2018).

[2] Rose A. Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65 Morbidity & Mortality Weekly Report 1445-52 (2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm (hereinafter "Rudd, *Increases in Drug and Opioid-Involved Overdose*").

[3] And nearly half of those involve legal opioids prescribed by doctors to treat pain.

prescription opioids.[4] Public health officials have called the current epidemic the worst drug crisis in American history.[5]

3. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is one of the main drivers of this epidemic. Prescription opioids have historically been used for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are, by their very nature, highly addictive and dangerous, the U.S. Food and Drug Administration ("FDA") regulates them as Schedule II Controlled Substances, *i.e.*, drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

4. This demonstrated need for caution comports with the historical understanding of both the medical community and the American culture at large regarding the serious consequences of opioid use and misuse. Indeed, thousands of years of experience have taught that opium's ability to relieve pain comes at a steep price; it is a dangerously addictive and often lethal substance. For generations, physicians were taught that opioid painkillers were highly addictive and should be used

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[4] That number does not take into account the staggering number of additional illicit opioid deaths that can be related back to doctor-prescribed opioids; indeed, four out of five new heroin users began first with prescription opioid misuse. Christopher M. Jones, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002-2004 and 2008-2010*, 132 (1-2) Drug & Alcohol Dependence 95-100 (Sept. 1, 2013), http://www.drugandalcoholdependence.com/article/S0376-8716(13)00019-7/fulltext. Still, most misused prescription drugs are obtained directly or indirectly from a doctor's prescription; only 4 percent of persons misusing or addicted to prescription drugs reports getting them from a drug dealer or stranger. Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 18 (Johns Hopkins University Press 2016) (hereinafter "Lembke, *Drug Dealer*"). "Unintentional poisoning deaths" from prescription opioids quadrupled between 1999 and 2010, outnumbering deaths from heroin and cocaine combined. Kathleen Frydl, *Purdue Pharma: Corporate Fraud With a Body Count*, Alternet (May 18, 2016), http://www.alternet.org/drugs/purdue-pharma-corporate-fraud-body-count (hereinafter "Frydl, *Purdue Pharma*").

[5] Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.

sparingly and primarily for patients near death.[6] The medical community also understood that opioids were poorly suited for long-term use because tolerance would require escalating doses and dependence would make it extremely difficult to discontinue their use.

5. However, the prevailing and accurate understanding of the risks and benefits of long-term opioid use limited drug manufacturers' ability to drive sales. In order to decrease reasonable concerns about opioids and to maximize profits, opioid manufacturers, including Defendants Purdue, Janssen, Endo, Cephalon, Insys and Mallinckrodt (individually defined in §II *infra*) (collectively, the "Manufacturing Defendants") engaged in a concerted, coordinated strategy to shift the way in which doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic pain conditions.

6. Borrowing from the tobacco industry's playbook, the Manufacturing Defendants employed ingenious marketing strategies, as detailed further herein, designed to "reeducate" the public and prescribers. They deliberately conceived these strategies to create, and in fact did create, an entirely new "health care" narrative – one in which opioids are considered safe and effective for long-term use, and pain is aggressively treated at all costs. According to this newly fabricated narrative, pain was seriously under-treated throughout the U.S. because opioids were under-prescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids.

7. The Manufacturing Defendants' intention was to normalize aggressive prescribing of opioids for chronic pain by downplaying the very real risks of opioids, especially the risk of addiction, and by exaggerating the benefits of use for chronic pain. To accomplish this goal, they intentionally misled doctors and patients about the appropriate uses, risks, safety and efficacy of

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[6] Harriet Ryan, et al., *OxyContin goes global – "We're only just getting started*," L.A. Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter "Ryan, *OxyContin goes global*").

prescription opioids. They did so directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, hospitals, the trade association for state medical boards and seemingly neutral third-party foundations. False messages about the safety, addictiveness, and efficacy were disseminated by infiltrating professional medical societies and crafting and influencing industry guidelines in order to disseminate false and deceptive pro-opioid communiques under the guise of science and truth.

8. The Manufacturing Defendants assured the public and prescribers that the risk of becoming addicted to prescription opioids among patients being treated for pain was less than 1%. In reality, many people with no addiction history can become addicted after just days or weeks of use.[7] Estimates for the risk of addiction range up to 56% of patients receiving long-term prescription opioid painkillers.[8] Indeed, almost one in five people who take an opioid for only ten days will still be taking opioids one year later.[9] The following chart[10] illustrates the degree to which the risk of dependency exists even after just several days of opioid therapy:

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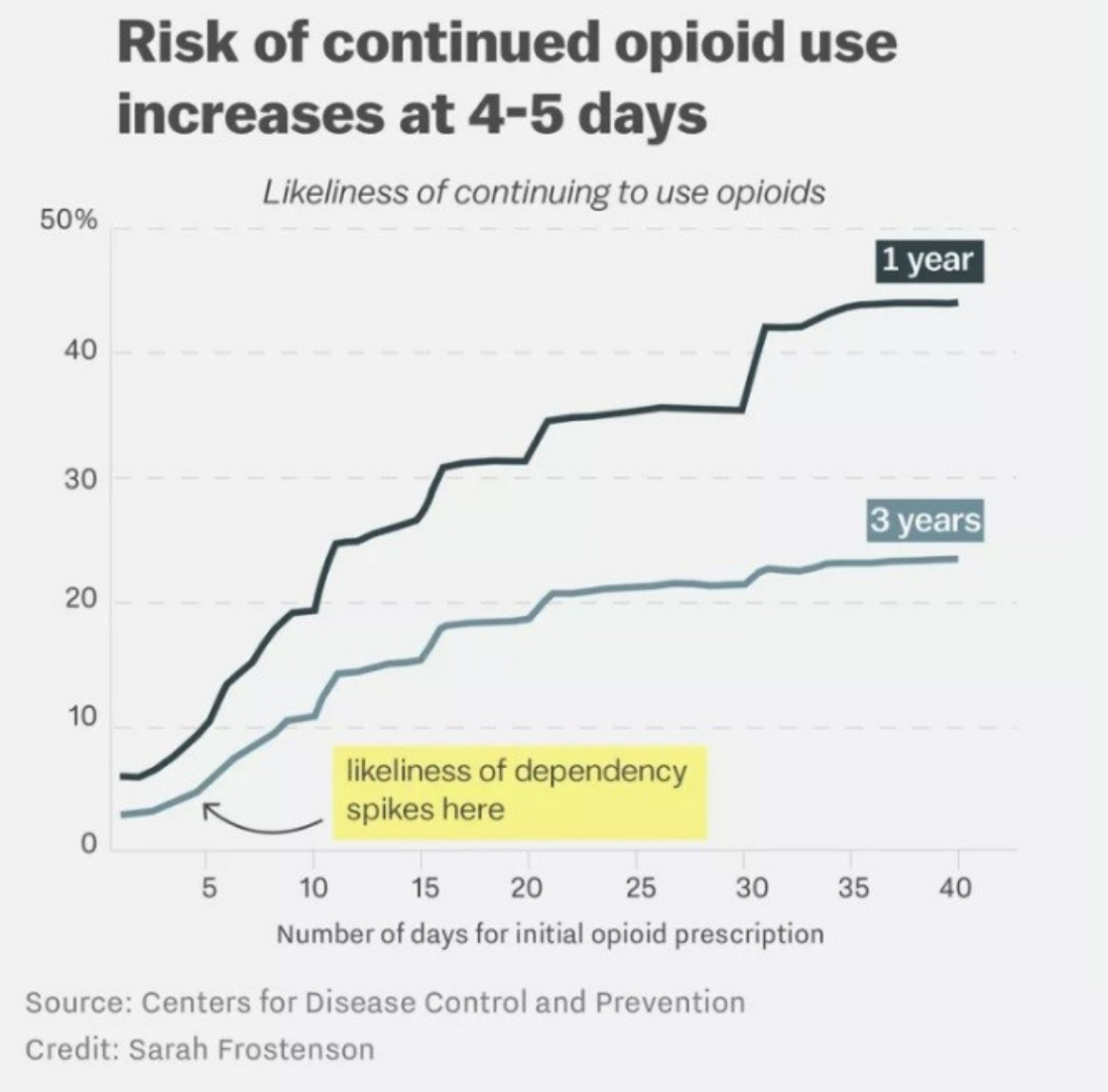
[7] Lembke, *Drug Dealer*, *supra* n.4, at 22.

[8] Bridget A. Martell, et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-pain-prevalence-efficacy-association (hereinafter, "Martell, *Systematic Review*").

[9] Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 20107, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioid-overuse-prescribe-them-for-3-days-or-less.

[10] German Lopez & Sarah Frostenson, *How the opioid epidemic became America's worst drug crisis ever, in 15 maps and charts*, Vox (Mar. 29, 2017), https://www.vox.com/science-and-health/2017/3/23/14987892/opioid-heroin-epidemic-charts.



9. In essence, the Manufacturing Defendants manipulated and misrepresented medical science to serve their own agenda at great human cost:[11]

[11] Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Annu. Rev. Public. Health 559-74 (2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

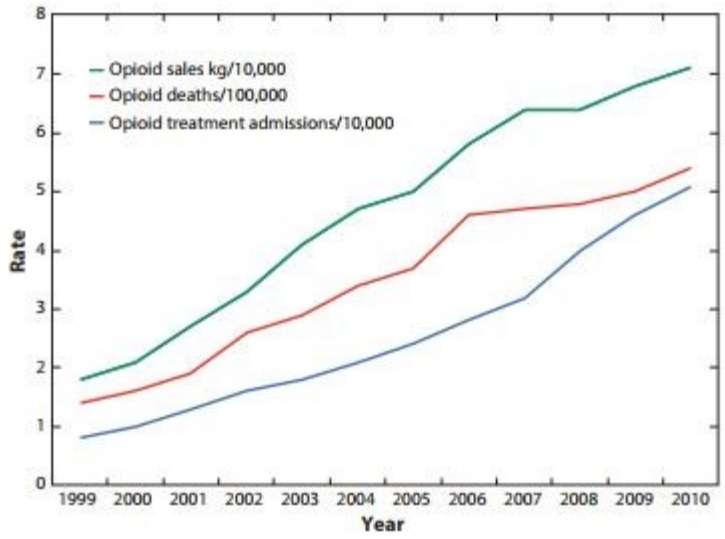


Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

10. Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal Health") and AmerisourceBergen Corporation ("AmerisourceBergen") (collectively, the "Wholesaler Defendants") are major distributors of controlled substances that act as middlemen between drug companies and pharmacies. Not just the Manufacturing Defendants, but also the Wholesaler Defendants were aware of a growing epidemic from the addiction to, and abuse of, prescription opioids they supplied. The Manufacturing Defendants and the Wholesaler Defendants were aware of the quantities and frequency with which those drugs were distributed to the beneficiaries of Plaintiffs. However, both the Manufacturing Defendants and the Wholesaler Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failure to follow the law significantly contributed to soaring addiction and overdose rates among the beneficiaries of Plaintiffs.

11. Plaintiffs have not only paid for opiates prescribed to their participants and covered dependents under these false pretenses, but now have faced massive costs in attempting to remediate the crisis as it destroyed their participants' lives and families.

12. The Wholesaler Defendants' violations have already led to fines elsewhere. McKesson, the largest prescription drug wholesaler company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government for such misconduct. In December 2016, Cardinal Health reached a $44 million settlement with the federal government. One month later, Cardinal Health reached a $20 million settlement with the State of West Virginia, which has been among the states hardest hit by opioid abuse. AmerisourceBergen also recently agreed to pay West Virginia $16 million for similar violations.[12]

13. Defendants' scheme was met with tremendous success, if measured by profit. According to *Fortune* magazine, McKesson, AmerisourceBergen and Cardinal Health are each among the top 15 companies in the Fortune 500. The Sackler family, which owns Purdue – a privately held company – is listed on *Fortune*'s list of America's wealthiest families; its "ruthless marketing of painkillers has generated billions of dollars – and millions of addicts."[13] However, the impact of opioid addiction has devastated the nation, emerging as one of the country's major health threats. As reported by *National Public Radio*, opioid addiction is thought to be among factors contributing to the United States' increase in overall rate for mortality from 2014 to 2015, the first time in a decade that the mortality rate increased. The mortality rate increased again in 2016. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein, that "mistake" resulted in large part from Defendants' false and misleading messaging, which was carefully

[12] Charles Ornstein, *Drug Distributors Penalized For Turning Blind Eye In Opioid Epidemic*, National Public Radio (Jan. 27, 2017), http://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic.

[13] Patrick R. Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (hereinafter, "Keefe, *Empire of Pain*").

calculated to reach as many prescribers as possible, and willingness to turn a blind eye to suspicious orders.

14. Even where some Defendants have previously been forced to admit the unlawful marketing and sale of opioids and/or the failure to report suspicious orders, the conduct does not abate because profits realized by the aggressive marketing and prescribing of opioids dwarf the penalties imposed as a result of violations found. Thus, the incentive to push opioids remains. The scheme was so financially successful, in fact, that despite the clear and obvious devastation it caused at home, Purdue's owners, the Sackler family, are now pursuing the same strategy abroad. As reported by the *Los Angeles Times*, Purdue states "[w]e're only just getting started," and intends to "[p]ut the painkiller that set off the United States opioid crisis into medicine cabinets around the world. A network of international companies owned by the family is moving rapidly into Latin America, Asia, the Middle East, Africa and other regions, and pushing for broad use of painkillers in places ill-prepared to deal with the ravages of opioid abuse and addiction."[14]

II. PARTIES

15. Plaintiff Cleveland Bakers & Teamsters is a multi-employer trust fund established to provide health and welfare benefits to collectively bargained members represented by Bakers' Union Local No. 19 and Teamsters Local Union No. 507, with its principal office located at 9665 Rockside Road in Valley View, Ohio, 44125. Cleveland Bakers & Teamsters indirectly purchased, paid and reimbursed for opioids intended for consumption by its covered participants, their dependents, and covered retirees. Given the Plan participants', covered dependents', and retiree's past history purchases of opioids, Cleveland Bakers & Teamsters anticipates that it will continue to purchase and/or provide reimbursement for opioids in the foreseeable future.

[14] Ryan, *OxyContin goes global*, *supra* n.6.

16. Plaintiff Pipe Fitters is a defined benefit health and welfare plan covering individuals represented by Pipe Fitters Local Union No. 120 located primarily in Northeastern Ohio. Pipe Fitters indirectly purchased, paid and/or reimbursed for opioids intended for consumption by its participants', covered dependents', and retiree and their families. Given it's the Plan participants', covered dependents', and retirees' history of purchases of opioids, Pipe Fitters anticipates that it will continue to purchase and/or provide reimbursement for opioids in the foreseeable future.

17. Defendant Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters located in Stamford, Connecticut. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P. and Purdue Products L.P. (referred to collectively herein as "Purdue").

18. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania. Cephalon, Inc. was acquired by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") in October 2011. Teva Ltd. is incorporated under the laws of Israel with its principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon, Inc., its United States sales and marketing activities have been conducted by Teva Pharmaceuticals USA, Inc. ("Teva USA" and, together with Teva Ltd., "Teva"), a wholly owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Cephalon, Inc. and Teva are collectively referred to herein as "Cephalon."

19. Defendant Endo International plc is an Irish public limited company with its headquarters in Dublin, Ireland. Defendant Endo Health Solutions Inc. is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals Inc. (together with Endo International plc and Endo Health Solutions Inc., "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern,

Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly wholly owned subsidiary of Endo International plc.

20. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") (formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica) is headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

21. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

22. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Defendant Mallinckrodt Pharmaceuticals (together with Mallinckrodt plc, "Mallinckrodt") is a Delaware corporation with its headquarters in Hazelwood, Missouri.

23. Defendant AmerisourceBergen Corp. is a Delaware corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania. Defendant AmerisourceBergen Drug Corp. is a subsidiary of AmerisourceBergen Corp.

24. Defendant McKesson Corporation is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California.

25. Defendant Cardinal Health, Inc. is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio.

III. JURISDICTION AND VENUE

26. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§1331 and 1332, as the claims are brought pursuant to the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1961, *et seq*. ("RICO").

27. Venue is proper pursuant to 28 U.S.C. §1391 and 18 U.S.C. §1965. Plaintiffs are headquartered in this District, have numerous beneficiaries in this District and have expended funds on behalf of those beneficiaries, along with beneficiaries throughout the country, they now seek to recoup. Further, a substantial part of the events or omissions giving rise to the claims occurred in this District, and each Defendant transacted affairs and conducted activity that give rise to the claims of relief in this District. This Court has personal jurisdiction over each Defendant as each purposefully availed itself of the privilege of exploiting forum-based business opportunities, each has submitted to jurisdiction of this state when obtaining a manufacturing or distributor license and each has the requisite minimum contacts with this state, making the exercise of personal jurisdiction consistent with Constitutional bounds.

IV. FACTUAL ALLEGATIONS

A. Over the Course of More than Two Decades, the Manufacturing Defendants Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates to Soar

28. From the mid-90s to the present, the Manufacturing Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis.

1. Background on Opioid Over-prescribing

29. The Manufacturing Defendants' scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called evidence. First was the publication of a 100-word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980

Letter to the Editor").[15] A recent article about the 1980 Letter to the Editor, titled "A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever," quoted a 2017 study in the *New England Journal of Medicine*, in which researchers concluded:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[16]

30. Second was a single medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[17] Portenoy emerged as one of the industry's

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[15] The 1980 Letter to the Editor, by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"), reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980). However, the letter did not support the conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter may have launched the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 (hereinafter "Jacobs, *One-paragraph letter*"). As discussed in a 2009 article in the *American Journal of Public Health*, the 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/ (hereinafter "Van Zee, *Promotion and Marketing*").

[16] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioid-epidemic-letter-1980-study.

[17] In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have

most vocal proponents of long-term opioid use, who essentially made it his life's work to campaign for the movement to increase use of prescription opioids. He was one of Big Pharma's[18] "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by the Manufacturing Defendants and organizations paid by them as continuing medical education ("CME") programs for doctors. He had financial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[19]

31. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis noted the important and detrimental role played by the 1980 Letter to the Editor and the Portenoy Publication. In a section of the Commission's Report with header "Contributors to the Current Crisis," the Commission wrote the following:

> **Unsubstantiated claims:** One early catalyst can be traced to a single letter to the Editor of the New England Journal of Medicine published in 1980, that was then cited by over 600 subsequent articles. With the headline "Addiction Rare in Patients Treated with Narcotics," the flawed conclusion of the five-sentence letter was based on scrutiny of records of hospitalized patients administered an opioid. It offered no information on opioid dose, number of doses, the duration of opioid treatment, whether opioids were consumed after hospital discharge, or long-term follow-up, nor a description of criteria used to designate opioid addiction. Six years later, another problematic study concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse." High quality evidence demonstrating that opioids can be used safely for chronic non-terminal pain did not exist at that time. These reports eroded the historical evidence (see Appendix 2) of iatrogenic addiction and aversion to opioids, with the poor-quality evidence that was unfortunately accepted by federal agencies and other oversight organizations.[20]

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to be performed. None was. *See* Russell K. Portenoy & Kathleen M. Foley, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25(2) Pain 171-86 (May 1986).

[18] "Big Pharma" is used herein to refer to large pharmaceutical companies considered especially as a politically influential group.

[19] Lembke, *Drug Dealer*, *supra* n.4, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).

[20] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/ files/images/Final_Report_Draft_11-1-2017.pdf.

32. Portenoy has now admitted that he minimized the risks of opioids.[21] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. ***In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind***.[22]

33. The damage, however, was already done. The Manufacturing Defendants used these two publications, the 1980 Letter to the Editor and the Portenoy Publication, as the foundation for a massive, far-reaching campaign to dramatically shift the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioid therapy. By 1997, the APS and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturing Defendants) issued a "landmark consensus," co-authored by Portenoy, stating there is little risk of addiction or overdose in pain patients.[23]

34. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturing Defendants introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and OxyContin in 1995, Janssen introduced Duragesic in 1990 and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana

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[21] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter "Gounder, *Who Is Responsible*").

[22] Jacobs, *One-paragraph letter*, *supra* n.15; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4.

[23] Jacobs, *One-paragraph letter*, *supra* n.15.

and Opana ER were approved by the FDA in 2006, as was Janssen's Nucynta in 2008 and Nucynta ER in 2011, Cephalon's Fentora in 2006 and Insys' Subsys in 2012.

35. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

36. Despite the prescription opioids' highly addictive qualities, the Manufacturing Defendants launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. Contrary to what doctors had previously understood about opioid risks and benefits, they were encouraged for the last two decades by the Manufacturing Defendants to prescribe opioids aggressively and were assured, based on false evidence provided directly by the Manufacturing Defendants and numerous medical entities funded by the Manufacturing Defendants and others with financial interests in generating more opioid prescriptions, that: (i) the risk of becoming addicted to prescription opioids among patients being treated for pain was low, even as low as less than 1%; and (ii) great harm was caused by "under-treated pain." These two foundational falsehoods led directly to the current opioid crisis.

37. The strategy was a brilliant marketing success. It was designed to redefine back pain, neck pain, headaches, arthritis, fibromyalgia and other common conditions suffered by most of the population at some point in their lives as a distinct malady – chronic pain – that doctors and patients should take seriously and for which opioids were an appropriate, successful and low-risk treatment.

Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer pain.[24]

38. This false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[25]

39. Despite the Manufacturing Defendants' representations to the contrary, there was no evidence of opioids' efficacy for the treatment of chronic pain. In fact, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was recently published on March 6, 2018, in *JAMA*. The trial, sponsored by the U.S. Department of Veterans Affairs ("Veterans Affairs"), was a randomized, 12-month study of 240 patients at Veterans Affairs primary care clinics. Each of the eligible patients had moderate to severe chronic back pain or hip or knee osteoarthritis despite the use of analgesic drugs.

40. The researchers reported that "[t]here was no significant difference in pain-related function between the 2 groups" – those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen. As such, they concluded: "***Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months***."[26]

41. Thus, based on false and incomplete evidence, the Manufacturing Defendants expanded their market exponentially from patients with end-stage cancer and acute pain, an

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[24] Ryan, *OxyContin goes global*, *supra* n.6.

[25] Lembke, *Drug Dealer*, *supra* n.4, at 22 (citing Martell, *Systematic Review*, *supra* n.8).

[26] Erin E. Krebs, et al., *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain, The SPACE Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, "Krebs, *Effect of Opioid vs. Nonopioid Medications*").

obviously limited customer base, to anyone suffering from chronic pain, which by some accounts includes approximately 100 million Americans – nearly one-third of the country's population.[27] The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made Defendants billions of dollars. It has also led to the opioid addiction and overdose crisis.

2. The Fraudulent Sales Practices

42. As set forth below, the Manufacturing Defendants employed a variety of strategies to normalize the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risk of addiction, overdose and death.

a. The Manufacturing Defendants Funded Front Organizations that Published and Disseminated False and Misleading Marketing Materials

43. The Manufacturing Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Manufacturing Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

44. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. Defendants Purdue, Cephalon and Endo have provided substantial funding to the FSMB.

[27] *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine, http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer (last visited Mar. 11, 2018).

45. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to ***700,000*** practicing doctors.

46. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain:

- Pain management is integral to good medical practice and for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;
- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

* * *

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. ***Misunderstanding of addiction and dependence***; and
4. Lack of understanding of regulatory policies and processes.[28]

47. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[29] Indeed, it

[28] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).

[29] *Id*. at 9.

states that even for those patients assessed to have risk of substance abuse, "it does not mean that opioid use will become problematic or that opioids are contraindicated," just that physicians should use additional care in prescribing.

48. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction."[30] It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction and states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[31] The guide, sponsored by the Manufacturing Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

49. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, ***it's critical to remember that the problem of unrelieved pain remains as urgent as ever***.[32]

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[30] *Id*. at 62.

[31] *Id*.

[32] Scott M. Fishman, *Responsible Opioid Prescribing: A Guide for Michigan Clinicians*, 10-11 (Waterford Life Sciences 2012).

50. The updated guide still assures that "***[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins***."[33]

51. In another guide by Fishman, he continues to downplay the risk of addiction: "***I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict***."[34] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

52. The heightened focus on the under-treatment of pain was a concept designed by Big Pharma to sell opioids. ***The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain***.[35] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," which wholly lacked scientific evidence but quickly became a common way for the Manufacturing Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox later became a Purdue vice president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University[36]: "'If I gave you a stalk of celery and you ate that, it would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good.'"[37]

53. As noted in ¶¶89-101 and 107-119 *infra*, in 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

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[33] *Id*. at 11.

[34] Scott M. Fishman, *Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication* 45 (Oxford University Press 2012).

[35] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.

[36] Gounder, *Who Is Responsible*, *supra* n.21.

[37] Keefe, *Empire of Pain*, *supra* n.13.

54. On June 8, 2012, the FSMB submitted a letter to the U.S. Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.[38] While the letter acknowledged the escalation of drug abuse and related deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated, "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" has been distributed in each of the 50 states and the District of Columbia.

55. In addition, the FSMB letter disclosed payments the FSMB received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through the present. Included in the payments received are the following payments from Defendants:

Company	***Fiscal Year***	***Amount***
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00
	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	***$822,400.06***
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Total Endo Payments	***$371,620.00***

[38] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley.

Company	*Fiscal Year*	*Amount*
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	***$180,000.00***
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	***$100,000.00***

56. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing."

57. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturing Defendants, including Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective vital sign) that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the danger of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

58. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies claiming "***there is no evidence that addiction is a significant issue when persons are given opioids for pain control***." The book was sponsored by Purdue.

59. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[39]) collaborated to issue a 101-page monograph titled "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous":

[39] Currently funded by Johnson & Johnson, Purdue and Teva, among others.

> Societal issues that contribute to the undertreatment of pain include drug abuse programs and erroneous beliefs about tolerance, physical dependence, and addiction (see I.E.5). For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction.
>
> * * *

b. Etiology, issues, and concerns

> Many medications produce tolerance and physical dependence, and some (*e.g.*, opioids, sedatives, stimulants, anxiolytics, some muscle relaxants) may cause addiction in vulnerable individuals. Most experts agree that ***patients who undergo prolonged opioid therapy usually develop physical dependence but do not develop addictive disorders. In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low***. A recent study of opioid analgesic use revealed "low and stable" abuse of opioids between 1990 and 1996 despite significant increases in opioids prescribed. . . .
>
> ***Fear of causing addiction (i.e., iatrogenic addiction), particularly with opioid use, is a major barrier to appropriate pain management. This fear sometimes reflects a lack of understanding of the risk of addiction with therapeutic drug use. Although studies suggest that the risk of iatrogenic addiction is quite low*** (e.g., Perry and Heidrich, Zenz et al.)***, surveys indicate that clinicians often overestimate this risk***.[40]

60. Additionally, the monograph recommends that "[p]ain . . . is assessed in all patients" and suggests that long-acting (*i.e.*, extended release) pain medications are superior and should be used whenever possible:

> ***Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain*** and often allow the patient to sleep through the night.
>
> * * *
>
> - Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.[41]

In truth, such medications often do not last as long as promised, and there is evidence to suggest that the use of long-acting drugs may actually create more addicts.

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[40] *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).

[41] *Id*. at 38, 67 (Table 38).

61. The Manufacturing Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[42] Consistent with the guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[43]

62. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[44]

63. **The American Pain Foundation**: The American Pain Foundation ("APF") described itself as the nation's largest organization for pain patients.[45] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from Defendants Purdue, Endo, Janssen and Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of APF's promotion of prescription opioids.

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[42] Lembke, *Drug Dealer*, *supra* n.4, at 119.

[43] *Id*. at 42.

[44] Gounder, *Who Is Responsible*, *supra* n.21; U.S. General Accounting Office, GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

[45] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.

64. The APF's guides for patients, journalists and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[46]

65. For example, in 2001, APF published "Treatment Options: A Guide for People Living with Pain."[47] The guide, which was produced due to support from companies including Defendants Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "***[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings*** as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[48]
- stated that "[o]pioids are an essential option for treating ***moderate*** to severe pain associated with surgery or trauma";[49] and
- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[50]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[51]

66. In 2003, APF published a newsletter titled "Best of . . . The Pain Community News" that purported to clarify any confusion over addiction and opioids and emphasized the "tragic

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[46] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/ (hereinafter "Ornstein, *American Pain Foundation*").

[47] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatment options.pdf (last visited Mar. 11, 2018).

[48] *Id*. at 11.

[49] *Id*.

[50] *Id*. at 15.

[51] *Id*. at 76.

consequence of leaving many people with severe pain under-treated because they – or their doctors – fear that opioids will cause addiction."

67. In 2009, Endo sponsored APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"), a book described as "the inspirational story of how one courageous veteran, with the aid of his family, recovered and thrived despite near death, traumatic brain injury, and the loss of a limb." It also purported to "offer[] veterans and their families comprehensive and authoritative information on . . . treatment options, and strategies for self-advocating for optimal pain care and medical resources inside and outside the VA system."

68. Among other false statements, Exit Wounds reported: "Long experience with opioids shows that ***people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications***." Endo, through APF, thus distributed false information with the purpose of providing veterans false information they could use to "self-advocat[e]" for opioids while omitting a discussion of the risks associated with opioid use.

69. In 2009, APF played a central role in a first-of-its-kind web-based series called "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

> [**Teresa Shaffer (APF Action Network Leader)**:] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [**Dr. Al Anderson (AAPM Board of Directors)**:] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a

> doctor ***when they are suffering from pain for a long period of time***, especially ***moderate*** to severe pain. And ***that's the patients that we really need to use the opioids*** methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to be controlled enough so that they can increase their quality of life.[52]

70. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[53] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and may actually reduce function.[54] As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions."[55] More recent still, a study published in *JAMA* concluded that "[t]reatment with opioids was ***not***

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[52] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.

[53] Lembke, *Drug Dealer*, *supra* n.4, at 59 (citing *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, Evidence Report/Technology Assessment, No. 218, Agency for Healthcare Research and Quality (Sept. 2014), https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/chronic-pain-opioid-treatment_executive.pdf).

[54] Discussing the CDC's "March 2016 Guideline for Prescribing Opioids for Chronic Pain," doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or quality of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), http://www.nejm.org/doi/full/10.1056/NEJMp1515917?af=R&rss=currentIssue&# t= article (footnote omitted).

[55] Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016), http://www.nejm.org/doi/full/10.1056/NEJMra1507771#t=article.

superior to treatment with nonopioid medications for improving pain-related function over 12 months."[56]

71. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website called www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. In a brochure available on painknowledge.org titled "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.

72. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "***common misconception***[]":

> ***Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive***. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[57]

73. The guide describes "pain in America" as "an evolving public health crisis" and characterizes concerns about opioid addiction as misconceptions: "Unfortunately, too many Americans are not getting the pain care they need and deserve. Some common reasons for difficulty

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[56] Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.26.

[57] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5 (Oct. 2011), http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

in obtaining adequate care include: . . . ***Misconceptions about opioid addiction***."[58] It even characterizes as a "***myth***" that "***[c]hildren can easily become addicted to pain medications***."[59] The guide further asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health and health-related quality of life for chronic pain patients, which was not the case.[60]

74. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed APF's close ties to drugmakers:

> ***[T]he pills continue to have an influential champion in the American Pain Foundation***, which describes itself as the nation's largest advocacy group for pain patients. ***Its message: The risk of addiction is overblown, and the drugs are underused***.
>
> ***What the nonprofit organization doesn't highlight is the money behind that message***.
>
> ***The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions***, an examination by ProPublica found.[61]

75. **American Academy of Pain Medicine and American Pain Society**: The Manufacturing Defendants, including at least Endo, Janssen and Purdue, have contributed funding to the AAPM and the APS for decades.

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[58] *Id*. at 6.

[59] *Id*. at 40.

[60] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, ***the other analgesics were significantly more effective than were opioids***." Andrea D. Furlan, et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/ pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

[61] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

76. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The chairman of the committee that issued the statement, Haddox, was, at the time, a paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the 1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

77. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by Veterans Affairs adopting that campaign as part of their national pain management strategy.

78. AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines received funding from Defendants Janssen, Cephalon, Endo or Purdue.

79. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[62] The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain*, have been cited hundreds of times in academic literature and remain available online. The Manufacturing Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions.

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[62] Roger Chou, et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter "Chou, *Clinical Guidelines*").

80. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[63] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[64] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list includes Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon.

81. APA's board members have also directly received substantial funding from pharmaceutical companies.[65] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from Defendants Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[66] Other board members include Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments by Defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Defendants Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015

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[63] *About AfPA*, The Alliance for Patient Access, http://allianceforpatientaccess.org/about-afpa/#membership (last visited Mar. 11, 2018). References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[64] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter "Jaklevic, *Non-profit Alliance for Patient Access*").

[65] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, *available at* https://projects.propublica.org/docdollars/.

[66] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), http://www.kansascity.com/news/business/health-care/article162569383.html.

from pharmaceutical companies, including Defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

82. Among its activities, APA issued a white paper titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[67] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
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> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> . . . We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[68]

83. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping

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[67] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[68] *Id*. at 4-5 (footnote omitted).

> and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[69]

84. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management – a situation fueled by the numerous regulations and fines that surround prescription pain medications.[70]

85. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[71]

86. The APA also issues "Patient Access Champion" financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a $7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients' access to Medicare, and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA's agenda.[72]

87. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of

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[69] *Id*. at 5-6.

[70] *Id*. at 6.

[71] *Id*. at 7.

[72] Jaklevic, *Non-profit Alliance for Patient Access*, *supra* n.64.

1970, 21 U.S.C. §801, *et seq*. ("CSA" or "Controlled Substances Act").[73] The AAPM is also a signatory to this letter. An internal DOJ memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[74] and, according to DEA chief administrative law judge John J. Mulrooney ("Mulrooney"), the law would make it "all but logically impossible" to defend prosecutions of manufacturers and distributors, like Defendants here, in the federal courts.[75] The law passed both houses of Congress and was signed into law in 2016.

88. ***Exposing the Financial Ties Between Opioid Manufacturers and Third Party Groups***: A February 23, 2018 report, titled "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" and issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's Office, sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[76]

89. The report details findings resulting from subpoenas issued by Senator McCaskill to five opioid manufacturers, including three of the Manufacturing Defendants – Purdue, Janssen,

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[73] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015), http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_Access_Letter_of_Support_House_Bill.pdf.

[74] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, *Opioid Crisis Fueled by Drug Industry*").

[75] John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101(2) Marquette L. Rev. 333-451 (Winter 2017), http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=5348&context=mulr.

[76] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, at 1 (Feb. 13, 2018), https://www.hsgac.senate.gov/download/fueling-an-epidemic-exposing-the-financial-ties-between-opioid-manufacturers-and-thirdparty-advocacy-groups, at 1.

Insys, Depomed and Mylan N.V. ("Mylan") – and to 15 purportedly neutral patient advocacy organizations and medical professional societies. "The information produced to the Committee demonstrates that many patient advocacy organizations and professional societies focusing on opioids policy have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers," the report found. It continued: "Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[77]

90. The five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

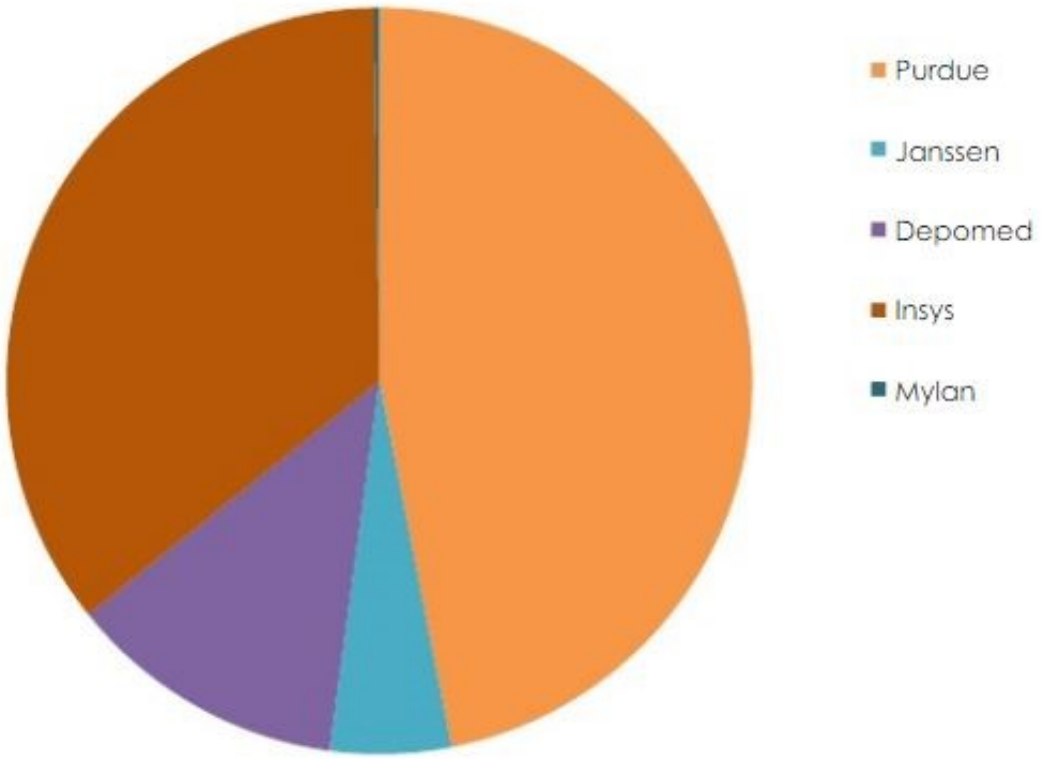
[77] *Id*. at 3.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	$1,265,566.81
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	$1,199,409.95
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	$304,605.00
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	$168,500.00
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	$417,140.00
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	$11,785.00
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	$25,000.00
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	$962,724.52
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	$30,000.00
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	$323,212.85
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	$163,095.00
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	$562,500.00
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	$2,922,800.00
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	$500,000.00
	$4,153,554.33	$465,152.85	$1,071,116.95	$3,146,265.00	$20,250.00	$8,856,339.13

91. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount:

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



92. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	$4,153,554.33
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				$465,152.85
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	$1,071,116.95
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	$3,146,265.00
Mylan				$15,000.00	$2,500.00	$2,750.00	$20,250.00
Total	$1,151,250.71	$1,275,878.00	$1,086,251.95	$1,830,369.00	$878,824.99	$2,633,764.48	$8,856,339.13

93. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members and advisory board members. When payments

from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

94. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Endo, Purdue and Mallinckrodt, to ten members of the American Chronic Pain Association Advisory Board; $170,000 from Insys to National Pain Foundation ("NPF") chairman and founder D. Daniel Bennett; and more than $950,000 to members of the NPF board of directors from various opioid manufacturers, including more than $250,000 from Insys alone.

95. Worse still, the organizations provided limited disclosures of these sources of funding – when they provided any information at all. The American Society of Pain Educators, the NPF, and the Academy of Integrative Pain Management provided no information concerning their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any

information concerning donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specifics as donation amounts.

96. Most importantly, many of the groups investigated "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[78] The report provided details regarding four ways the groups investigated set about these tasks.

97. First, the report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain."[79] The report provides examples, including: (i) the AAPM's and APS's 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low; (ii) the 2009 issuance of guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history; (iii) the 2009 issuance of guidelines by the American Geriatrics Society ("AGS") for the management of persistent pain recommending that opioids should be considered for all patients with moderate to severe pain in older patients and stating that the risks of addiction are exceedingly low in older patients; and (iv) the creation of a 2009 patient education guide by the AGS, the AAPM and Janssen stating that opioids are rarely addictive when used properly to manage chronic pain.

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[78] *Id*. at 12.

[79] *Id*.

98. Second, the report notes that "[a]dvocacy groups have engaged in extensive lobbying efforts to either defeat legislation restricting opioid prescribing or promote laws encouraging opioid treatment with pain."[80] For example, in 2014 the Academy of Integrative Pain Management and the American Cancer Society Cancer Action Network led the effort to protect a law making it difficult to discipline doctors for over-prescribing opioids and prohibited doctors from refusing to prescribe opioids unless they also referred the patient to an "opioid-friendly" doctor.

99. Third, the report criticized a majority of the groups for strongly criticizing CDC guidelines issued in 2016 providing prescribing recommendations for primary care doctors who are prescribing opioids for chronic pain outside of active treatment of cancer, palliative care and end-of life care. These guidelines were "'the first national standards for prescription painkillers'" and were "perhaps the first major step from the federal government [] toward limiting opioid prescriptions for chronic pain in the face of an unprecedented public health crisis."[81] However, most industry groups opposed the guidelines. For example, David Carr, the immediate past president of the AAPM, criticized the guidelines as reflecting "'disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.'" Other groups complained that draft guidelines "were not transparent," cited purported conflicts of interest among those who created them, criticized the "'overly secretive manner'" in which they'd been developed, and called them "'inherently biased.'"[82]

100. Fourth, several of the advocacy groups and professional societies organized legal efforts to challenge government actions to punish executives responsible for fraudulent opioid marketing and doctors who over-prescribed opioids. For example, the NPF submitted an *amicus* brief to the U.S. Court of Appeals for the Fourth Circuit in support of a doctor convicted of 16

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80 *Id*. at 13.

81 *Id*. at 13-14.

82 *Id*. at 14.

counts of drug trafficking for prescribing massive quantities of oxycodone and other narcotics – in one instance, more than 1,600 per day – to patients in chronic pain. In its brief, the NPF opposed the conviction, criticizing the holding that "'a doctor acting in the good faith belief that he was serving the best medical interest of his patient could be found to be a drug dealer.'"[83] The Washington Legal Foundation filed an *amicus* brief in the U.S. Court of Appeals for the District of Columbia Circuit arguing that the exclusion of three former Purdue executives from participation in federal healthcare programs for 12 years for their admitted failure to prevent fraudulent marketing of OxyContin raised "serious constitutional due process concerns."

101. In conclusion, the report found that, while health advocacy organizations are "'among the most influential and trusted stakeholders in U.S. health policy,'" the reality is that their "'positions closely correspond to the marketing aims of pharmaceutical and device companies,'" including in the area of opioids policy. "The findings in this report indicate that this tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[84]

b. The Manufacturing Defendants Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging

102. The Manufacturing Defendants have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Recently released federal data shows that the Manufacturing Defendants increased such payments to physicians who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs,

[83] *Id*. at 15.

[84] *Id*. at 17.

such as heroin, soared to record rates.[85] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs and other freebies. The total payments from the Manufacturing Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[86] Physicians who are high prescribers are more likely to be invited to participate in Defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[i]n the speakers' bureau system, physicians are recruited and trained by pharmaceutical, biotechnology, and medical device companies to deliver information about products to other physicians, in exchange for a fee."[87]

103. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. According to a 2013 publication by the Institute on Medicine as a Profession, speakers' bureaus are ethically compromised because they often present information as objective when it is heavily biased toward the interests of the industry sponsor and, in fact, may lead to the dissemination of false or biased information. These findings are substantiated by citations to research in *JAMA*, *The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*.

The Problem:

> ***Pharmaceutical companies often recruit physicians to perform speeches or presentations for the purpose of marketing a specific drug. In 2010, 8.6% of physicians reported having received payments for participating in speakers' bureaus***. These speakers' bureaus leverage the credibility of physicians in order to promote the use of pharmaceutical products. ***The physicians are generally trained to present a certain message, or are provided with pre-produced slides. The audience may assume that these presentations are objective, when in fact they are heavily biased towards the interests of the industry sponsor***.

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[85] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.

[86] *Id*.

[87] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

> ***Speakers' bureaus may lead to the dissemination of false or biased information***. Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing. Additionally, the compensation provided for these engagements may influence the attitudes or judgment of the presenter.[88]

104. For example, Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM, and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[89]

105. Similarly, Fine's ties to the Manufacturing Defendants have been well documented.[90] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity

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[88] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf.

[89] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13) JAMA 1445 (2011); Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter "Weber, *Two Leaders in Pain*").

[90] Weber, *Two Leaders in Pain*, *supra* n.89.

Anna Nicole Smith for pain did not make her an addict before her death.[91] He has also acknowledged having failed to disclose numerous conflicts of interest.

106. Fishman and Fine are only two of the many physicians whom the Manufacturing Defendants paid to present false or biased information on the use of opioids for chronic pain.

c. Senate Investigations of the Manufacturing Defendants

107. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin and Opana.

108. The Senate Finance Committee sent letters to Purdue, Endo and Johnson & Johnson, as well as five groups that support pain patients, physicians or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission.

109. As shown below in an excerpt from the Senators' letter to APF, the Senators addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible:

> ***It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers such as Oxycontin (oxycodone), Vicodin (hydrocodone), Opana (oxymorphone)***. According to CDC data, "more than 40% (14,800)" of the "36,500 drug poisoning deaths in 2008" were related to opioid-based prescription painkillers. Deaths from these drugs rose more rapidly, "from about 4,000 to 14,800" between 1999 and 2008, than any other class of drugs, [killing] more people than heroin and cocaine combined. ***More people in the United States now die from drugs than car accidents as a result of this new epidemic. Additionally, the CDC***

[91] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), http://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

reports that improper "use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs."

* * *

Concurrent with the growing epidemic, the New York Times reports that, based on federal data, "***over the last decade, the number of prescriptions for the strongest opioids has increased nearly fourfold, with only limited evidence of their long-term effectiveness or risks" while "[d]ata suggest that hundreds of thousands of patients nationwide may be on potentially dangerous doses***."

There is growing evidence pharmaceutical companies that manufacture and market opioids may be responsible, at least in part, for this epidemic by promoting misleading information about the drugs' safety and effectiveness. Recent investigative reporting from the Milwaukee Journal Sentinel/MedPage Today and ProPublica revealed extensive ties between companies that manufacture and market opioids and non-profit organizations such as the American Pain Foundation, the American Academy of Pain Medicine, the Federation of State Medical Boards, and University of Wisconsin Pain and Policy Study Group, and the Joint Commission.

In a ProPublica story published in the Washington Post, the watchdog organization examined the ***American Pain Foundation, a "health advocacy" organization that received "nearly 90 percent of its $5 million funding from the drug and medical device industry***." ProPublica wrote that its review of the American Pain Foundation's "guides for patients, journalists, and policymakers ***play down the risks associated with opioids and exaggerate their benefits***. Some of the foundation's materials on the drugs include statements that are misleading or based on scant or disputed research."

According to the Milwaukee Journal Sentinel/MedPage Today, a "***network of national organizations and researchers with financial connections to the makers of narcotic painkillers . . . helped create a body of dubious information" favoring opioids "that can be found in prescribing guidelines, patient literature, position statements, books and doctor education courses***."[92]

Although it is critical that patients continue to have access to opioids to treat serious pain, ***pharmaceutical companies and health care organizations must distribute accurate and unbiased information about these drugs in order to prevent improper use and diversion to drug abusers***.[93]

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[92] For example, the *Sentinel* reported that the FSMB, with financial support from opioid manufacturers, distributed "[m]ore than 160,000 copies" of a model policy book that drew criticism from doctors because "it failed to point out the lack of science supporting the use of opioids for chronic, non-cancer pain." John Fauber, *Follow the Money: Pain, Policy, and Profit*, MedPage Today (Feb. 19, 2012), http://www.medpagetoday.com/Neurology/PainManagement/31256.

[93] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society (footnote added).

110. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to physicians, including Portenoy, Fishman and Fine, among others. They asked about any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." The opioid report resulting from this investigation has not been released publicly.[94]

111. On March 29, 2017, it was widely reported[95] that yet another Senate investigation had been launched:

> Missouri Senator Claire McCaskill has launched an investigation into some of the country's leading prescription drug manufacturers, demanding documents and records dating back the past five years which indicate just what the companies knew of the drugs' risk for abuse as well as documents detailing marketing practices and sales presentations. Her office has sent letters to the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

112. The above-referenced companies were reportedly targeted based on their role in manufacturing some of the opioid painkillers with the highest sales in 2015.

113. On September 6, 2017, Senator McCaskill's report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization" was published. The report found that Insys manipulated the prior authorization process by misleading pharmacy benefit managers about the role of Insys in the prior authorization process and the presence of breakthrough cancer pain in potential Subsys patients.[96]

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[94] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.46.

[95] Nadia Kounang, *Senator McCaskill opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), http://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

[96] HSGAC Minority Staff Report, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (2017).

114. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.
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> * * *
>
> Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed.

115. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing. She, too, placed the blame for the opioid crisis squarely at the feet of pharmaceutical companies:

> Since the 1990's, pharmaceutical companies have stealthily distorted the perceptions of consumers and healthcare providers about pain and opioids. Opioid manufacturers use drug reps, physicians, consumer groups, medical groups, accreditation and licensing bodies, legislators, medical boards and the federal government to advance marketing goals to sell more opioids. This aggressive marketing pushes resulted in hundreds of thousands of deaths from the overprescribing of opioids. The U.S. is about – comprises about five percent of the world population, but we use about two-thirds of the world supply of opioids.

116. Fugh-Berman also answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

117. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry-influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis. They persuaded prescribers that patients with pain were somehow immune to addiction. Even when addiction was suspected, physicians were taught that it might not really be addiction, it might be pseudo-addiction, an invented (ph) condition that's treated by increasing opioid dosages.
>
> Industry created the American Pain Foundation co-opted other groups including medical organizations, and they change state laws to eliminate curbs on opioid prescribing. Between 2006 and 2015, pharmaceutical companies and the advocacy groups they control employ 1,350 lobbyists a year in legislative hubs. Industry-influenced regulations and policies ensure that hospitalized patients were and are berated paraded constantly about their level of pain and overmedicated with opioids for that pain. Even a week of opioids can lead a patient into addiction so many patients are discharged from hospitals already dependent on opioids.

118. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

119. Fugh-Berman concluded by stating: "It is a misperception to think that most opioid deaths are caused by misuse of opioids or overdoses. In fact, many deaths occur when people are using opioids in exactly the way they were prescribed. Misuse isn't the problem; use is the problem."

3. The Devastating Impact

120. The impact of the Manufacturing Defendants' false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and

died of overdoses.[97]

121. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, to $3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.

122. The United States is experiencing an unprecedented opioid addiction and overdose epidemic, costing billions of dollars for, *inter alia*, treatment, services and public safety, as well as lost productivity in the workforce and economic opportunity.

123. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical users of OxyContin."[98]

124. By 2004, OxyContin had "become the most prevalent prescription opioid abused in the United States."[99] The severity of the problem was first felt in states including Maine, West Virginia, eastern Kentucky, southwestern Virginia and Alabama, where, from 1998 through 2000, hydrocodone and oxycodone were being prescribed 2.5-5 times more often than the national average. By 2000, these same areas had a prescription rate up to 5-6 times higher than the national average. These areas were also the first to suffer increased abuse and diversion, which became apparent by 1999 and 2000. Manufacturers then expanded the geographic market by investing hundreds of millions of dollars in marketing, and the once-regional problem began to spread nationally. "[B]y 2004 OxyContin had become a leading drug of abuse in the United States."[100]

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[97] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), http://www.vox.com/2016/2/5/10919360/opioid-epidemic-chart.

[98] Van Zee, *Promotion and Marketing*, *supra* n.15.

[99] *Id*.

[100] *Id*.

125. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%) and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).[101]

126. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[102] In 2014, there were more than 47,000 drug overdose deaths nationwide, 61% involving a prescription or illicit opioid.[103] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[104]

B. The Manufacturing Defendants' Specific Unlawful Practices that Targeted Prescribers

1. Purdue

127. Purdue manufactures, markets, sells and distributes opioids nationwide, including the following:

OxyContin (oxycodone hydrochloride extended release)	Opioid agonist[105] indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II

[101] Gounder, *Who Is Responsible*, *supra* n.21.

[102] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.

[103] Rudd, *Increases in Drug and Opioid-Involved Overdose*, *supra* n.2.

[104] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter "Eban, *Painful Medicine*").

[105] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to illicit a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*, https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb (last visited Mar. 11, 2018).

MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.	Schedule II
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.[106]	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate that is indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II

a. Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs

128. Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[107] Prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[108] In its initial press release launching the drug, Purdue told doctors that one OxyContin tablet would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and on Purdue's repeated assurances that opioids were both effective and non-

[106] *Dilaudid Addiction*, Suboxone California, https://www.suboxonecalifornia.com/suboxone-treatment/dilaudid-addiction (last visited Mar. 11, 2018).

[107] Harriet Ryan, et al., "*You Want A Description of Hell?*" *OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter "Ryan, *Description of Hell*").

[108] Keefe, *Empire of Pain*, *supra* n.13.

addictive, OxyContin became America's bestselling painkiller.[109] Purdue had no evidentiary basis for those claims.[110]

129. In truth, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early, as Purdue's own early studies showed, it is highly addictive:

> OxyContin's stunning success masked a fundamental problem: The drug wears off hours early in many people, a Los Angeles Times investigation found. ***OxyContin is a chemical cousin of heroin, and when it doesn't last, patients can experience excruciating symptoms of withdrawal, including an intense craving for the drug***.[111]

130. Furthermore, experts call the 12-hour dosing "'an addiction producing machine.'"[112] Purdue had reportedly known for decades that it falsely promised 12-hour relief and nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

- . . . Even before OxyContin went on the market, ***clinical trials showed many patients weren't getting 12 hours of relief***. Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales reps and independent research.

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[109] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996), https://www.freelibrary.com/NEW+HOPE+FOR+MILLIONS+OF+AMERICANS+SUFFERING+FROM+PERSISTENT+PAIN%3A…-a018343260.

[110] Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . . The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency shortly afterward. Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.13.

[111] The *Los Angeles Times* investigation, reported in three parts on May 5, July 10 and December 18, 2016, included the review of thousands of pages of confidential Purdue documents and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn testimony by executives, sales representatives and other employees. Ryan, *Description of Hell*, *supra* n.107. The *Los Angeles Times* reporters also examined FDA records, Patent Office files and medical journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. *Id*.

[112] Frydl, *Purdue Pharma*, *supra* n.4.

- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price – up to hundreds of dollars per bottle – hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.

- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.

- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.

- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for The Times.[113]

131. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue promised the long-acting, extended-release formulation as safer and "less prone to such problems."[114]

b. Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians

132. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk, Purdue also promoted the use of prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.[115]

133. Rather than targeting merely those physicians treating acute severe short-term (like post-operative) pain or oncologists treating end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin nationwide to doctors such as general practitioners, who often had

[113] Ryan, *Description of Hell*, *supra* n.107.

[114] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter "Meier, *Guilty Plea*").

[115] Ornstein, *American Pain Foundation*, *supra* n.46.

little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[116] According to a report in *The New Yorker*, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, fibromyalgia" and "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[117]

134. Sales representatives plied these and other physicians with coupons that were redeemable for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent,'" and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic non-cancer-related pain."[118]

135. Sales representatives marketed OxyContin as a product "'to start with and to stay with,'" and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine.[119] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[120]

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[116] Meier, *Guilty Plea*, *supra* n.114.

[117] Keefe, *Empire of Pain*, *supra* n.13.

[118] Van Zee, *Promotion and Marketing*, *supra* n.15.

[119] Keefe, *Empire of Pain*, *supra* n.13.

[120] *Id.*

136. Further, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)"[121]

137. Even as late as 2015, if not later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had "'abuse deterrent' properties."[122]

138. The marketing worked. Keith Humphreys, Professor of Psychiatry at Stanford and drug-policy adviser to the Obama Administration, said, "'[t]hat's the real Greek tragedy of this – that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling. Purdue gave money to continuing medical education, to state medical boards, to faux grassroots organizations.'"[123]

139. Purdue also tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from I.M.S. Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. (Notably, Arthur Sackler co-founded I.M.S. Health.) Rather than reporting highly suspicious prescribing practices, Purdue used the data to track physicians who prescribed some opioids and might be persuaded to prescribe more. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.[124] It called the high-prescribing doctors "whales."[125]

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[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan, et al., *More than 1 million OxyContin pills ended up in the hands of criminals*

140. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[126] Since 2002, Purdue maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had reported only 8% of them to authorities. The *Los Angeles Times* reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[127]

c. Purdue Funded Publications and Presentations with False and Misleading Messaging

141. As explained above, Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials. It extended far beyond, engaging third parties including doctors and front groups to spread the false message of prescription opioids' safety and efficacy.

142. Purdue caused the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors.

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and addicts. What the drugmaker knew, L.A. Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/ (hereinafter, "Ryan, *More than 1 million*").

[125] Keefe, *Empire of Pain*, *supra* n.13.

[126] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015, 3:32 PM), http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrict-marketing-of-6464800.php.

[127] Ryan, *More than 1 million*, *supra* n.124.

143. One of the advisors for Fishman's 2007 publication "Responsible Opioid Prescribing: A Physician's Guide" and its 2012 update was Haddox, a longtime member of Purdue's speakers' bureau who later became a Purdue vice president.

144. Similarly,[128] multiple videos feature Fine delivering educational talks about the drugs. In one video from 2011 titled "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy" discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[129] He states the "goal is to improve effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events ***over the course of years***." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat ***sleep apnea***. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[130]

145. Purdue provided many "teaching" materials free of charge to the Joint Commission.

146. Purdue also deceptively marketed the use of opioids for chronic pain through the APF, which was shut down after the Senate investigation launched in 2012. In 2010 alone, the APF received 90% of its funding from drug and medical device companies, including from Purdue.

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[128] Weber, *Two Leaders in Pain*, *supra* n.89.

[129] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

[130] *Id*.

Purdue paid APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[131]

d. The Guilty Pleas

147. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell ("Udell"), Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

148. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. ***Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.***
>
> ***But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures***. . . . OxyContin was the child of marketeers and bottom line financial decision making.[132]

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[131] American Pain Foundation Partner Report, GuideStar, http://www.guidestar.org/PartnerReport.aspx?ein=52-2002328&Partner=Demo (last visited Mar. 11, 2018) (links to annual reports at bottom of page).

[132] Press Release, U.S. Department of Justice, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), http://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

149. Brownlee characterized Purdue's criminal activity as follows:

> First, ***Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse***. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, ***Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction*** than immediate-release opioids.
>
> Third, ***Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse*** than short-acting opioids.
>
> Fourth, ***Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance*** to the drug.
>
> And fifth, ***Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids***, and could be used to "weed out" addicts and drug seekers.[133]

150. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin, for introducing misbranded drugs into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

151. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive. Purdue continues to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007,

> it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers,

[133] *Id*.

> along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.[134]

152. Purdue has earned more than $31 billion from OxyContin, the nation's bestselling painkiller, which constitutes approximately 30% of the United States market for painkillers. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up threefold from 2006 sales of $800 million.[135]

153. Purdue also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

154. Publicly disclosed payments for the years 2013 through 2016 reveal that Purdue made hundreds of individual payments for "food and beverage" expenses related specifically to programs about OxyContin and Hysingla ER.

e. Purdue Failed to Report Suspicious Sales as Required

155. The Controlled Substances Act, and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq*., imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

156. Purdue is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

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[134] Keefe, *Empire of Pain*, *supra* n.13.

[135] Eban, *Painful Medicine*, *supra* n.104.

157. Purdue failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue also failed to report to the board sales of dangerous drugs subject to abuse. Purdue's failure to timely report these and other suspicious sales violated the CSA.

2. Janssen

158. Janssen manufactures, markets, sells and distributes the following opioids nationwide:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

159. Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also markets Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen markets Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

a. The FDA Warned Janssen Regarding Its False Messaging

160. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq*. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

161. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

- You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine." Therefore, this claim is false or misleading.[136]

162. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

- You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means . . . ." Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the

[136] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica at 2 (Mar. 30, 2000).

> suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,
>
> > BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:
>
> - In the management of acute or post-operative pain, including use in out-patient surgeries . . . .[137]

163. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product":

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, ***you have not presented any risk information*** concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use . . . . Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.[138]

164. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

165. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

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[137] *Id*. at 2-3.

[138] *Id*. at 3 (emphasis in original).

> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.
>
> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.[139]

166. The September 2, 2004 letter also detailed a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including that:

- "'Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep.'"
- "'All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain.'"
- "'Significantly reduced nighttime awakenings.'"
- "'Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index.'"
- "'Significant improvement in physical functioning summary score.'"
- "'Significant improvement in social functioning.'"[140]

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[139] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. at 2 (Sept. 2, 2004), http://www.johnsonandtoxin.com/040920_duragesic_letter.pdf.

[140] *Id*. at 2-3.

167. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter stated: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[141]

168. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

b. Janssen Funded False Publications and Presentations

169. Despite these repeated warnings, Janssen continued to falsely market the risks of opioids. In 2009, PriCara, a "Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.," sponsored a 2009 brochure, "Finding Relief: Pain Management for Older Adults," aimed at potential patients. The brochure included a free DVD featuring actress Kathy Baker, who played a doctor in the popular television series "Picket Fences."

170. The brochure represented that it was a source for older adults to gain accurate information about treatment options for effective pain relief:

[141] *Id*. at 3.

> This program is aimed specifically at older adults and what they need to know to get effective pain relief. You will learn that there are many pathways to this relief.
>
> You will learn about your options for pain management and how to find the treatment that's right for you. By learning more about pain and the many ways it can be treated, you are taking solid steps toward reducing the pain you or a loved one may be feeling.[142]

171. Despite representing itself as a source of accurate information, the brochure included false and misleading information about opioids, including a section seeking to dispel purported "myths" about opioid usage:

> **Opioid Myths**
>
> **Myth**: Opioid medications are always addictive.
>
> **Fact**: Many studies show that opioids are ***rarely*** addictive when used properly for the management of chronic pain.
>
> **Myth**: Opioids make it harder to function normally.
>
> **Fact**: When used correctly for appropriate conditions, opioids may make it ***easier*** for people to live normally.
>
> **Myth**: Opioid doses have to get bigger over time because the body gets used to them.
>
> **Fact**: Unless the underlying cause of your pain gets worse (such as with cancer or arthritis), you will probably remain on the same dose or need only small increases over time.[143]

172. Among the "Partners" listed in "Finding Relief: Pain Management for Older Adults" are the AAPM, the AGS and the AGS Foundation for Health in Aging. Janssen (along with Purdue and Endo) funded the AAPM. The AGS and the AGS Foundation for Health in Aging published a pain guide titled "Finding Relief: Pain Management for Older Adults," which was funded by Janssen.[144]

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[142] *Finding Relief, Pain Management for Older Adults* (2009).

[143] *Id*. (emphasis in original).

[144] *Id*.

173. In addition, Janssen disseminated false information about opioids on the website Prescribe Responsibly, which remains publicly accessible at www.prescriberesponsibly.com. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[145] The website includes numerous false or misleading representations concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesic[] . . . therapy."[146]

174. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with NSAIDs, such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioid side effects:

> Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over nonsteroidal anti-inflammatory drugs (NSAIDs). Opioid analgesics, for example, have no true 'ceiling dose' for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[147]

175. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the

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[145] *Legal Notice*, Prescribe Responsibly, http://www.prescriberesponsibly.com/ legal-notice (last visited Mar. 11, 2018).

[146] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http:// www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Mar. 11, 2018).

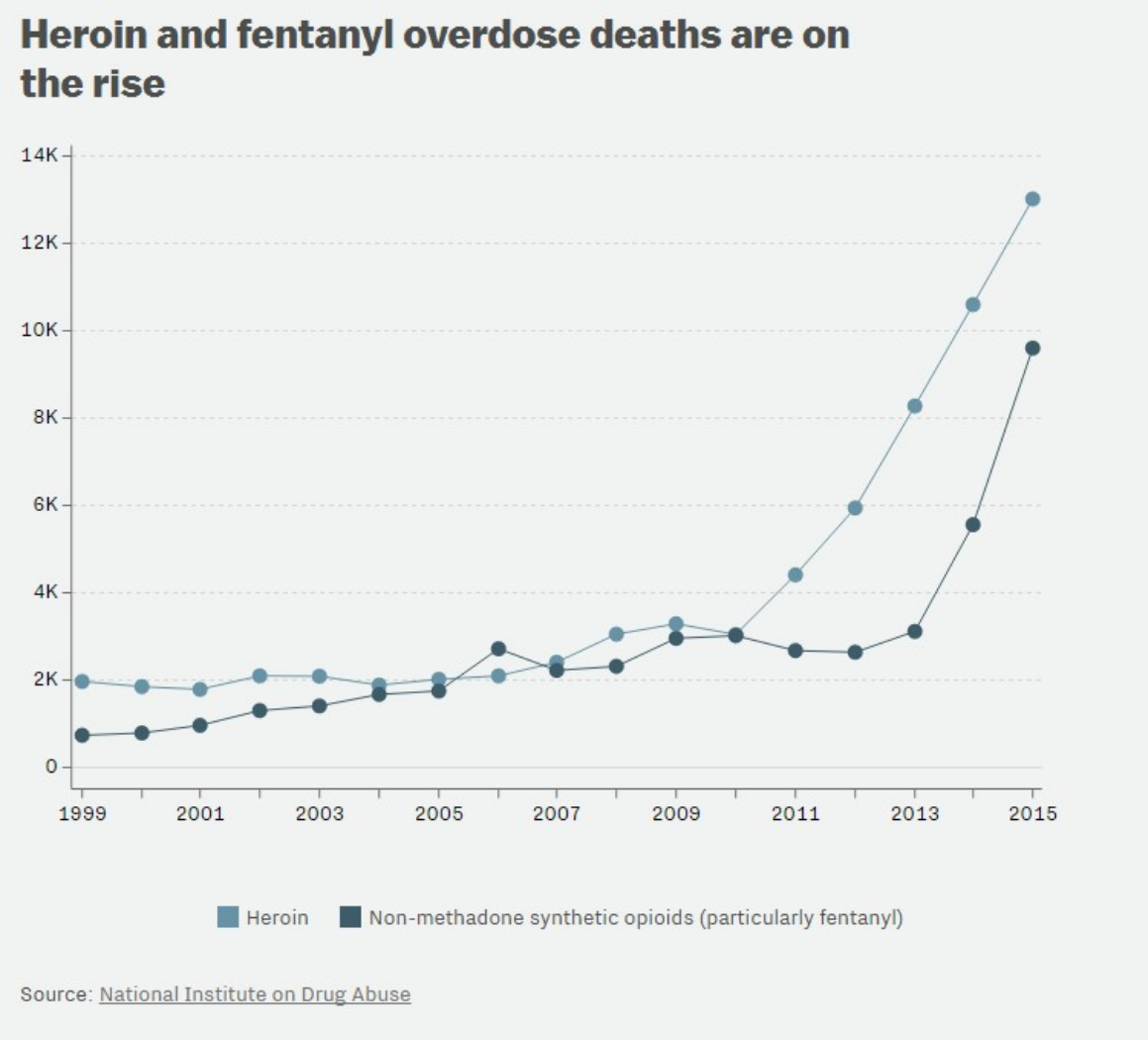
[147] *Id*.

inappropriate behavior ceases."[148] Thus, pseudoaddiction is defined as a condition requiring the prescription of more or stronger opioids.

176. Janssen also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services. Based on an analysis of publicly disclosed reports from the years 2013 through 2016, Janssen made payments to physicians for food and beverage expenses related to programs on Nucynta.

177. As people became more and more hooked on prescription pain killers, they moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and which as set forth above was being deceptively marketed by Janssen, causing a dramatic spike in heroin and fentanyl overdose deaths:

[148] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited Mar. 11, 2018).



c. Janssen Failed to Report Suspicious Sales as Required

178. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

179. Janssen is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

180. Janssen failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Janssen also failed to report to the board sales of dangerous drugs subject to abuse.

3. Endo

181. Endo manufactures, markets, sells and distributes the following opioids nationwide:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone is available in an oral, extended-release formulation; first approved in 2006.	Schedule II
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
Oxycodone	Generic product.	Schedule II
Oxymorphone	Generic product.	Schedule II
Hydromorphone	Generic product.	Schedule II
Hydrocodone	Generic product.	Schedule II

182. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated "for the relief of moderate to severe pain" and "for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[149]

183. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid

[149] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com /watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-in-trials-b99494132z1-303198321.html/.

is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus it was marketed as being safer, with less abuse potential than OxyContin because of its crush-resistance.

184. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

a. Endo Falsely Marketed Opana ER as Crush Resistant

185. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the latter "'is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets.'"

186. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release. In a December 12, 2011, press release announcing FDA approval of the reformulated Opana ER, Endo's executive vice president for research and development and chief scientific officer highlighted the reformulated version's safety characteristics:

> "FDA's approval of this new formulation of Opana ER is an important milestone for both the Long Acting Opioid category as well as Endo's branded pharmaceutical portfolio. . . . Patient safety is our top concern and addressing

> appropriate use of opioids is a responsibility that we take very seriously. We firmly believe this new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."

187. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned: "'Clearly, we are looking into this data, . . . but it's in a very, very distinct area of the country.'"[150]

188. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "'cutting, grinding, or chewing,'" "'can be prepared for insufflation (snorting) using commonly available tools and methods,'" and "'can [be readily] prepared for injection.'" It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

189. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, it also found that injection had become the preferred way of abusing the drug.[151] However, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

190. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a

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[150] Tom Dreisbach, et al., *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/health-shots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

[151] *Id.*

large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[152] The CDC specifically attributed the outbreak to the injection of Opana ER. As the advisory explained:

> From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.[153]

b. New York's Investigation Found Endo Falsely Marketed Opana ER

191. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[154] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

192. Among other things, the investigation concluded that:

- ***Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;***

- ***Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and***

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[152] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://emergency.cdc.gov/ han/han00377.asp (last visited Mar. 11, 2018).

[153] *Id.*

[154] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

- ***Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana E***R.

193. In October 2011, Endo's director of project management e-mailed the company that had developed the formulation technology for reformulated Opana ER to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

> "***We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference*** and this contributed to their statement that we had not shown an incremental benefit. ***The chewing study (109) showed the same thing no real difference*** which the FDA used to claim no incremental benefit."[155]

194. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract reformulated Opana ER than the original version, and whether it would take longer to extract from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

195. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "'[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant.'" The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[156]

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[155] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15, at 5 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_ AOD_030116-Fully_Executed.pdf.

[156] *Id*. at 6.

196. Regardless, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[157]

197. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

198. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

199. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "'Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.'"[158] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

200. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "'Symptoms of withdrawal do not indicate addiction.'"[159] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).

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[157] *Id.*

[158] *Id.*

[159] *Id.* at 7.

201. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. However, Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudoaddiction.

202. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder." If Endo does not comply with the request, Dr. Woodcock stated that the FDA would issue notice of a hearing and commence proceedings to compel its removal.

c. Endo Funded False Publications and Presentations

203. Like several of the other Manufacturing Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including APF.

204. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[160]

205. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by

[160] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/ BtoB_Opana_WM.pdf.

> patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[161]

206. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

207. Later, in 2014, Endo issued a patient brochure titled "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

208. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.

[161] *Id.*

- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.

* * *

Your doctor or nurse may instruct you to do some of the following:

- Take the next dose before the last dose wears off. If pain is present most of the day and night, the pain medicine may be taken at regularly scheduled times. If you are taking a short-acting opioid, this usually means taking it every 4 hours. You may need to set your alarm, especially at night, to be sure you take your dose before the pain returns and wakes you up.

- If your pain comes and goes, take your pain medicine when pain first begins, before it becomes severe.

- If you are taking a long-acting opioid, you may only need to take it every 8 to 12 hours, but you may also need to take a short-acting opioid in between for any increase in pain.[162]

209. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled "Screener and Opioid Assessment for Patients with Pain (SOAPP) Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[163] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

210. Endo also sponsored the now-defunct website painknowledge.com, which was created by APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management

[162] Margo McCaffery & Chris Pasero, *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf (emphasis in original).

[163] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https:// www.paineducators.org/wp-content/uploads/2012/12/ASPE-ResForEducationOn PainAn.pdf.

approaches."[164] Among other featured content, painknowledge.com included a flyer titled "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

211. Endo, along with Janssen and Purdue, also provided grants to APF to distribute Exit Wounds, discussed above. *See supra* ¶67.[165]

212. Endo also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

d. The FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse

213. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its risks."[166] According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. On July 6, 2017, Endo pulled Opana ER from the U.S. market.

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[164] *AboutPainKnowledge.org*, PainKnowledge, http://web.archive.org/web/20120120094923/http://www.painknowledge.org/aboutpaink.aspx (last visited Mar. 11, 2018).

[165] *Iraq War Veteran Amputee, Pain Advocate and New Author Release Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families*, Coalition for Iraq + Afghanistan Veterans, https://web.archive.org/web/20160804131030/http://coalitionforveterans.org/2009/10/iraq-war-veteran-amputee-pain-advocate-and-new-author-releases-exit-wounds-a-survival-guide-to-pain-management-for-returning-veterans-and-their-families/ (last visited Mar. 11, 2018).

[166] Press Release, U.S. Food & Drug Administration, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

e. Endo Failed to Report Suspicious Sales as Required

214. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

215. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

216. Endo failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also failed to report to the board sales of suspicious drugs subject to abuse.

4. Cephalon

217. Cephalon manufactures, markets, sells and distributes the following opioids nationwide:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain (or "BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

218. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense BTP in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,[167] rapidly into a patient's bloodstream through the oral membranes.[168] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[169]

219. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[170]

220. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[171] Further, the FDA explicitly stated that Actiq "***must not*** be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

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[167] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.opiates.com/media/narcotic-lollipop-becomes-big-seller-despite-fda-curbs/ (hereinafter "Carreyrou, *Narcotic Lollipop*").

[168] Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue or in the nose.

[169] *Cephalon, Inc.*, Company-Histories.com, http://www.company-histories.com/Cephalon-Inc-Company-History.html (last visited Mar. 11, 2018).

[170] 1998 FDA Label.

[171] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.

221. The FDA also required that Actiq be provided only in compliance with a strict risk-management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[172]

222. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

223. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a. Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians

224. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing its lollipop to treat headaches, back pain, sports injuries and other chronic non-cancer pain, targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

225. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits

[172] Carreyrou, *Narcotic Lollipop*, *supra* n.167.

to non-oncologists to pitch Actiq increased sixfold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[173]

226. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[174] By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[175] By 2005, Actiq's sales total had jumped to $412 million, making it (a drug approved for only a narrow customer base) Cephalon's second-best selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.[176]

227. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[177]

b. Government Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses

228. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-

[173] *Id.*

[174] *Id.*

[175] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

[176] Carreyrou, *Narcotic Lollipop*, *supra* n.167.

[177] *Id.*

approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, ***Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results***.[178]

229. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> "***This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line***. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved."[179]

230. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches;
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that

[178] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.

[179] *Id*.

Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;

- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and

- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[180]

231. Still, the letters, the FDA's safety alert, DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c. Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians

232. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors, falsely represented Fentora as a safe, effective off-label treatment for non-cancer pain and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

233. During an investor earnings call shortly after Fentora's launch, Cephalon's chief executive officer ("CEO") described the "opportunity" presented by the use of Fentora for non-cancer pain:

> ***The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain***.

[180] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, at B1 (hereinafter "Carreyrou, *Cephalon Used Improper Tactics*").

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> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[181]

d. The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora

234. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[182]

235. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[183] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a

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[181] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call (May 1, 2007), http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript.

[182] Press Release, U.S. Food & Drug Administration, Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007).

[183] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008), https://www.fda.gov/ohrms/dockets/ ac/08/slides/2008-4356s2-03-Cephalon.pdf.

risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

236. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

237. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

238. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

239. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[184]

[184] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

e. Cephalon Funded False Publications and Presentations

240. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain, that they were non-addictive and that they were woefully under-prescribed to the detriment of patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles and CME programs, and it paid physicians thousands of dollars every year to publicly opine that opioids were safe, effective and non-addictive for a wide variety of uses.

241. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

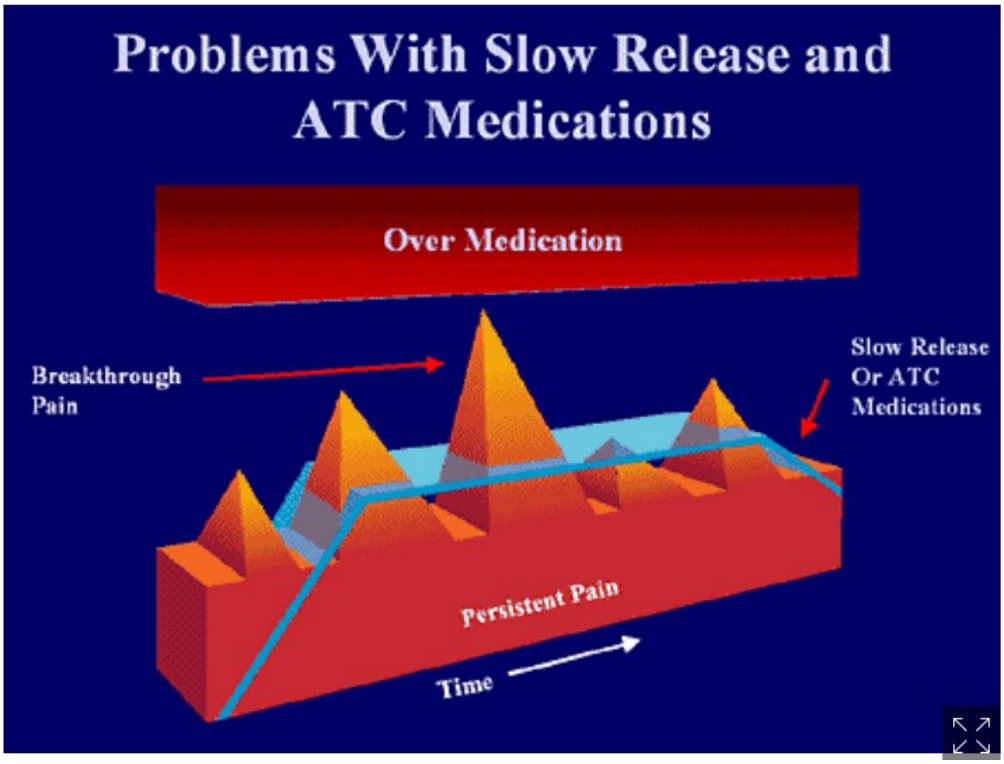
242. For example, a 2003 Cephalon-sponsored CME presentation titled "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, teaches:

> ***[C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse***.[185]

243. Another Cephalon-sponsored CME presentation titled "Breakthrough Pain: Treatment Rationale with Opioids" was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes,

[185] Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, https://www.medscape.org/viewarticle/449803 (last visited Mar. 11, 2018).

the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[186] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.



244. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate for the use of migraine headache pain and concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in

[186] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, https://www.medscape.org/viewarticle/461612 (last visited Mar. 11, 2018).

outpatients . . . and was associated with high patient satisfaction ratings."[187] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

245. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled "Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines."[188] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer-associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. ***Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients***.[189]

246. Deeper into the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "***[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain***." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, ***OTFC might also be used cautiously and safely for acute pain experienced by patients who are not opioid tolerant. Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant***. Examples include episodic pain (i.e., refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[190]

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[187] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004).

[188] Gerald M. Aronoff, et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).

[189] *Id*.

[190] *Id*.

247. Through its sponsorship of the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" (*see supra* ¶¶45-48), Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

248. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

249. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove titled "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007 through December 15, 2008. The presentation teaches that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.[191]

250. Fine authored a Cephalon-sponsored CME presentation titled "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report"

[191] Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, Medscape, http://www.medscape.org/viewarticle/563417_6 (last visited Mar. 11, 2018).

supplement of the journal *Pain Medicine News* in 2009.[192] The CME presentation targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME presentation purports to analyze the "combination of evidence- and case-based discussions" and ultimately concludes:

> Chronic pain is a debilitating biopsychosocial condition prevalent in both cancer and noncancer pain populations. . . . Opioids have an established role in pain related to cancer and other advanced medical illnesses, as well as an increasing contribution to the long-term treatment of carefully selected and monitored patients with certain [chronic noncancer pain] conditions. ***All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected***.[193]

251. Along with Purdue, Cephalon sponsored APF's guide (*see supra* ¶65), which warned against the purported ***under***-prescribing of opioids, taught that addiction is ***rare*** and suggested that opioids have "***no ceiling dose***" and are therefore the most appropriate treatment for severe pain.

252. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continues:

> ***Pain management is a fundamental human right*** in all patients not only with acute postoperative pain but also ***in patients suffering from chronic pain***. Treating the underlying cause of pain does not usually treat all of the ongoing pain. Minimal pathology with maximum dysfunction remains the enigma of chronic pain. Chronic pain is only recently being explored as a complex condition that requires individual treatment and a multidisciplinary approach. It is considered to be a disease entity.[194]

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[192] Perry G. Fine, et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain/9.

[193] *Id*.

[194] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).

253. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[195]

254. In the March 2007 article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[196] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients."[197] The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with ***chronic noncancer pain*** and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP ***and the potential benefits of BTP-specific therapy*** suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[198]

255. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. In a single 2008 issue of the journal, there are numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh") and Webster, all advancing the safety and efficacy of opioids. In an article titled "Screening and Stratification

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[195] *See* Chou, *Clinical Guidelines*, *supra* n.62.

[196] Donald R. Taylor, et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).

[197] *Id*.

[198] *Id*.

Methods to Minimize Opioid Abuse in Cancer Patients," Webster expresses disdain for the prior 20 years of opioid phobia.

256. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh state: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[199]

257. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[200] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain"; and (c) those

[199] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).

[200] Perry G. Fine, et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[201]

258. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." They also conclude that the number of abuse-related events was "small."[202]

259. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy and others.

260. Cephalon's payments to doctors have resulted in studies that support its sales but, on closer examination, are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[203] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice" and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[204]

261. Teva, which acquired Cephalon, has repeatedly refused to produce information requested as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent

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[201] *Id*.

[202] *Id*.

[203] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.180.

[204] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

September 28, 2017, Senator McCaskill explained that "'the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders.'" On March 6, 2018, Senator McCaskill issued a press release castigating Teva for its continued refusal to comply with her requests: "'Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide.'"[205]

f. Cephalon Failed to Report Suspicious Sales as Required

262. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

263. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

264. Cephalon failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

5. Insys

265. Insys manufactures, markets, sells and distributes the following pharmaceutical drug nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.	Schedule II

266. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their

[205] Press Release, McCaskill: Teva Is Stonewalling a Senate Investigation, U.S. Senate Committee on Homeland Security & Government Affairs (Mar. 6, 2018), https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation.

underlying persistent cancer pain."[206] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg and 800 mcg dosage strengths.

267. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys' sales of Subsys are through wholesalers, including Defendants AmerisourceBergen, McKesson and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17% and 14% of Insys' total gross sales of Subsys.

268. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[207]

269. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

270. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain,

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[206] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

[207] Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC (Nov. 5, 2015, 10:13 AM), http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html.

neck pain and other off-label pain conditions.[208] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of ***mild-to***-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[209] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

271. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[210]

a. The Indictment of Insys Executives and Arrest of Its Founder

272. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[211]

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[208] *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015), https://www.documentcloud.org/ documents/2195731-insysdoj.html.

[209] Portenoy's paper, "Breakthrough pain: definition, prevalence and characteristics," which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating') . . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 41(3) Pain 273-81 (July 1990).

[210] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/ business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html.

[211] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeer ing-scheme (hereinafter "Insys Indictment Press Release"); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, ECF No. 1 (D. Mass. Dec. 6, 2016), https:// www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter "*Insys* Indictment").

273. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and pharmacy benefit managers. Insys' reimbursement unit employees were told to inform agents of insurers and pharmacy benefit managers that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

274. The executive defendants in the indictment include John Kapoor ("Kapoor"), Insys' former CEO and president, as well as the company's former vice president of sales, former national director of sales, former vice president of managed markets and several former regional sales directors. On October 26, 2017, Kapoor – the billionaire founder, CEO and chairman of Insys, who owns a 60% stake in the company – was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer.[212]

275. The charges against all seven executives include alleged violations of the federal Anti-Kickback Law, the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers. If found guilty, the defendants face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the defendants face a sentence of up to five years in prison and a $25,000 fine.

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[212] Michela Tindera, *Opioid Billionaire Arrested On Racketeering Charges*, Forbes (Oct. 26, 2017), https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#1af3f9076a00.

276. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated and the patient's course of treatment with other medication.

277. Harold H. Shaw, special agent in charge of the FBI Boston field division, said in a statement, "'[a]s alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers.'"[213]

b. Insys Targeted Non-Cancer Treating Physicians and Funded False Publications and Presentations

278. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires, employing sales representatives and other employees at practitioners' behest and with the expectation that such hires would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

279. Specifically, in June 2012, former executives began using in-person meetings, telephone calls and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The

213 *Id.*

former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[214]

280. Speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

281. Moreover, the executives are charged with targeting practitioners who prescribed Subsys not only for cancer pain, but for all pain. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

> "These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug."[215]

282. The indictment also alleges that, when agents of insurers or pharmacy benefit managers asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "'The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).'"[216]

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[214] Insys Indictment Press Release, *supra* n.211.

[215] *Insys* Indictment, *supra* n.211, at 15.

[216] *Id*. at 44.

283. Insys' former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

284. In a press release issued when the indictment was announced, the Massachusetts U.S. Attorney, Carmen M. Ortiz, stated: "'I hope that today's charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street level dealing.'"[217]

285. In the same press release, the FBI Special Agent in charge of the Boston Field Division, Harold H. Shaw, linked the allegations to the national opioid epidemic:

> ***"As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to abuse and life threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts***."[218]

286. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "'Causing the unnecessary use of opioids by current and retired

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[217] Insys Indictment Press Release, *supra* n.211.

[218] *Id*.

U.S. military service members shows disregard for their health and disrespect for their service to our country . . . .'"[219]

287. On August 31, 2017, Arizona Attorney General Brnovich filed a lawsuit alleging violations of the ACFA by Insys, two of its former employees and three doctors.[220] Attorney General Brnovich alleged that Insys and its two named employees – former Vice President of Sales Alec Burlakoff and former Manager of Reimbursement Services Elizabeth Gurrieri – engaged in numerous deceptive or unfair acts and practices, including those related to:

- the use of the Insys Reimbursement Center ("IRC"), which was designed to obtain prior authorization for Subsys from insurers and pharmacy benefit managers, misleading consumers about the prior authorization process and the IRC's practices;
- failing to warn consumers about IRC practices, even though Insys knew or had reason to know that healthcare professionals using the IRC would not be in a position to reduce foreseeable risks of harm due to the IRC's practices;
- providing healthcare professionals with false and misleading information, and concealing, suppressing or omitting material facts about the definition of "breakthrough cancer pain" and the FDA-approved uses of Subsys, in order to deceive healthcare professionals so that they would prescribe more Subsys;
- failing to warn consumers of the foreseeable risks of harm from Subsys and Insys' practices while knowing or having reason to know that healthcare professionals to whom Insys provided false and misleading information would not be in a position to reduce the foreseeable risks of harm; and
- providing sham "speaker fees" to healthcare practitioners to induce, and in exchange for, the healthcare practitioners writing Subsys prescriptions.

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[219] *Id.*

[220] Press Release, Arizona Attorney General Mark Brnovich, AG Brnovich Files Lawsuit Against Opioid Manufacturer Insys Therapeutics and Three Arizona Doctors (Aug. 31, 2017), https://www.azag.gov/press-release/ag-brnovich-files-lawsuit-against-opioid-manufacturer-insys-therapeutics-and-three; *State of Arizona, ex rel. Brnovich v. Insys Therapeutics, Inc., et al*., No. CV2017-012008, Complaint for Injunctive and Other Relief (Ariz. Super. Ct., Maricopa Cty. Aug. 30, 2017), https://www.azag.gov/sites/default/files/sites/ all/docs/press-release/press-release-files/2017_Files/complaints/Insys_Complaint_8_30_17.pdf. On January 23, 2018, Attorney General Brnovich filed a motion seeking leave to amend the complaint.

288. According to the complaint, between March 2012 and April 2017, the three defendant doctors wrote more than $33 million worth of Subsys prescriptions while being paid, on average, approximately $200,000 each in "speaker fees" by Insys.

289. According to the complaint, in order to be booked as speakers and receive speaker fees, doctors were required to have at least 20 patients on Subsys. On the other hand, frequent prescribers of Subsys were "rewarded" by being paid in speakers fees, which served to "'notice[]'" "'their support of Subsys'" with "'positive reinforcement.'"

c. Insys Failed to Report Suspicious Sales as Required

290. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

291. Insys is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

292. Insys failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

6. Mallinckrodt

293. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

Among the drugs it distributes are the following:

Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.*, non-opioid analgesics) are inadequate. The FDA approved the 8, 12, and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.	Schedule II
Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues, and stars.	Schedule II
Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.	Schedule II
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.	Schedule II
Morphine sulfate extended release	Generic product.	Schedule II
Fentanyl extended release	Generic product.	Schedule II
Fentanyl citrate	Generic product.	Schedule II
Oxycodone and acetaminophen	Generic product.	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic product.	Schedule II
Hydromorphone hydrochloride	Generic product.	Schedule II
Hydromorphone hydrochloride extended release	Generic product.	Schedule II
Naltrexone hydrochloride	Generic product.	Schedule II
Oxymorphone hydrochloride	Generic product.	Schedule II
Methadone hydrochloride	Generic product.	Schedule II
Oxycodone hydrochloride	Generic product.	Schedule II

294. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[221]

295. Mallinckrodt debuted Xartemis (MNK-795) at the September 4-7, 2013 PAINWeek in Las Vegas.

a. Mallinckrodt Funded False Publications and Presentations

296. Like several of the other Manufacturing Defendants, Mallinckrodt provided substantial funding to purportedly neutral organizations that disseminated false messaging about opioids.

297. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[222]

298. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[223] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

299. Will you become dependent on or addicted to oxycodone?

- After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.

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[221] *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012), http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE.

[222] *Pain Treatment Topics*, Pain-Topics.org, https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/ (last visited Mar. 11, 2018).

[223] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

- This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[224]

300. Additionally, the FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[225]

301. Another document available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they

[224] *Id.*

[225] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20070709031530/http:// www.pain-topics.org:80/faqs/index1.php#tolerance (last visited Mar. 11, 2018).

are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[226]

302. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[227] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[228]

b. The DEA Investigates Suspicious Orders

303. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied – and failed to report – suspicious orders for its generic oxycodone between 2008 and 2012.[229] The U.S. Attorney's office in Detroit, handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[230] According to the internal government documents obtained by the Washington Post, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[231]

304. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise") of Broward

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[226] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, Pain-Topics.org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

[227] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, The Intercept (Apr. 4, 2017, 2:15 PM), https://theintercept.com/2017/04/04/scott-gottlieb-opioid/.

[228] *Id.*

[229] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.4aea01894ae2.

[230] *Id.*

[231] *Id.*

County, Mallinckrodt in the following six weeks sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 to a single patient.[232]

305. According to documents obtained by the Washington Post, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those violations included the failure to keep accurate records, to document transfers of drugs and to secure narcotics.[233]

306. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[234] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violations and an opportunity to comply, to pharmacies and distributors, before withdrawing licenses. This Act substantially lessened the DEA's ability to regulate manufacturers and wholesalers.[235]

307. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis,

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[232] *Id.*

[233] *Id.*

[234] *Sponsors: HDA's Annual Circle Sponsors*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/hda-sponsors (last visited Oct. 5, 2017).

[235] Chris McGreal, *Opioid epidemic: ex-DEA official says Congress is protecting drug makers*, Guardian (Oct. 31, 2016, 9:26 EDT), https://www. theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma.

McKesson, Mallinckrodt, AmerisourceBergen, and Qualitest – all of whom are conveniently missing from the list of those responsible.[236]

308. In April 2017, Mallinckrodt plc reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Michigan and Northern District of New York to pay $35 million to resolve a probe of its distribution of its opioid medications.[237] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[238]

c. Mallinckrodt Failed to Report Suspicious Sales as Required

309. The federal CSA imposes on all "registrants" the obligation to design and operate a system to disclose to the registrant suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

310. Mallinckrodt is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

311. Mallinckrodt failed to design and operate a system to disclose suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders.

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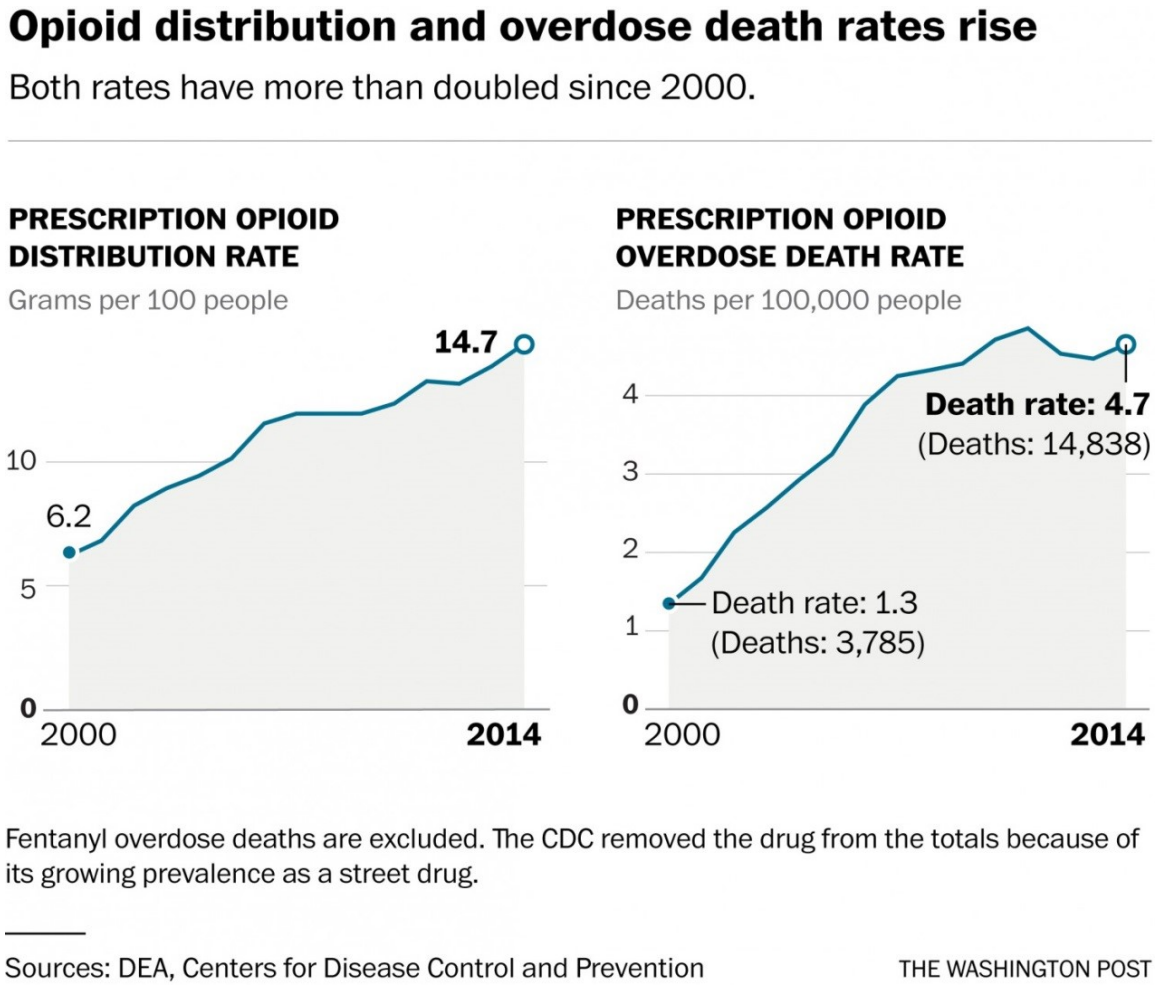
[236] National Association of Boards of Pharmacy, *Red Flags*, YouTube (May 20, 2014), https://www.youtube.com/watch?v=WY9BDgcdxaM.

[237] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. News & World Report (Apr. 3, 2017, 6:47 PM), https://www.usnews.com/ news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

[238] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/ opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

C. The Wholesaler Defendants Failed to Track and Report Suspicious Sales as Required by Federal Law

312. Manufacturers rely upon distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



313. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent Joe Rannazzisi ("Rannazzisi"), who blamed the Wholesaler Defendants for killing people by violating the CSA requirement to report suspicious orders:

> **JOE RANNAZZISI**: This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.

* * *

> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.
>
> **[INTERVIEWER]**: Who are these distributors?
>
> **JOE RANNAZZISI**: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> **[INTERVIEWER]**: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **JOE RANNAZZISI**: That's not an implication, that's a fact. That's exactly what they did.[239]

314. Jim Geldhof, a 40-year veteran of the DEA who ran investigations in the Detroit field office, corroborated Rannazzisi's account, saying that the wholesalers are "absolutely" responsible for the opioids epidemic:

> **[INTERVIEWER]**: These companies are a big reason for this epidemic?
>
> **JIM GELDHOF**: Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.[240]

315. Indeed, according to Rannazzisi, the Wholesaler Defendants succeeded in lobbying Congress to strip the DEA of its most potent tool for fighting against diversion and abuse. In 2013, a bill was introduced in the House that "was promoted as a way to ensure that patients had access to the pain medication they needed." What it "really did," however, "was strip the [DEA] of its ability to immediately freeze suspicious shipments of prescription narcotics to keep drugs off U.S. streets."

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[239] Whitaker, *Opioid Crisis Fueled by Drug Industry*, *supra* n.74.

[240] *Id*.

A 2015 DOJ memo confirmed that the bill "'could actually result in increased diversion, abuse, and public health and safety consequences.'"[241]

316. During the two years the legislation was considered and amended, Defendants and others in the industry spent $102 million lobbying Congress on the bill and other legislation, "claiming the DEA was out of control [and] making it harder for patients to get needed medication." The APA co-signed a letter in support of the legislation. As discussed *supra* ¶¶80-81, the APA receives funding from numerous industry participants, including Johnson & Johnson, Endo, Mallinckrodt, Purdue and Cephalon. Metadata associated with the letter co-signed by the APA shows that it was created by Kristen L. Freitas ("Freitas"), vice president for federal government affairs at the HDA – the trade group that represents Defendants McKesson, Cardinal Health and AmerisourceBergen. Freitas is also a registered lobbyist who lobbied in support of the bill.

317. According to *60 Minutes*, the chief administrative law judge of the DEA, Mulrooney, has written "that the new legislation 'would make it all but . . . impossible' to prosecute unscrupulous distributors."[242] The proposed bill was signed into law in 2016. The primary author of the bill is former DEA associate chief counsel Linden Barber. He was recently hired by Cardinal Health as senior vice president.

1. McKesson

318. McKesson is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical drug distributor in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

319. McKesson supplies various United States pharmacies an increasing amount of prescription opioids, products frequently misused that are at the heart of the current opioid epidemic.

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[241] *Id.*

[242] *Id.*

320. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

321. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

322. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

323. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys built a case against McKesson for the company's role in the opioid crisis, which David Schiller ("Schiller"), Assistant Special Agent in Charge for the Denver Field Division and leader of

the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."[243]

324. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> **DAVID SCHILLER**: If they woulda stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> **[INTERVIEWER**:] And they had none.
>
> **DAVID SCHILLER**: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[244]

325. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law. According to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program. As part of the agreement, McKesson acknowledged that:

> at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.

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[243] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.

[244] *Id.*

2. Cardinal Health

326. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over $121 billion.

327. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter and consumer products in the United States. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

328. Cardinal Health distributes pharmaceuticals through a network of distribution centers across the country. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue.

329. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

330. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.[245]

[245] Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that

331. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and
- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

332. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder").[246]

333. In the press release announcing the settlement agreement, Rosenstein stated:

> "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA . . . . Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."[247]

334. In the press release, Colder clarified that the settlement primarily concerned the opioid oxycodone:

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between 2008 and 2012 certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes.

[246] Press Release, U.S. Attorney's Office for the District of Maryland, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

[247] *Id.*

> "DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . . . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety . . . ."[248]

3. AmerisourceBergen

335. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the U.S. through a network of 26 pharmaceutical distribution centers.[249] It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

336. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

337. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and

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[248] *Id.*

[249] *AmerisourceBergen*, Wikipedia, https://en.wikipedia.org/wiki/Amerisource Bergen (hereinafter "*AmerisourceBergen*") (last visited Mar. 11, 2018); Drug Distribution Locations – Mainland US, https://batchgeo.com/map/ 788de3747b01802c0171abfa8a4b5eca (last visited Mar. 11, 2018).

Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[250] AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period.[251] Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. The Wholesaler Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

FIRST CAUSE OF ACTION

Negligence and Negligent Misrepresentation (Against the Manufacturing Defendants)

338. Plaintiffs incorporate by reference herein all of the allegations set forth above.

339. The Manufacturing Defendants failed to use reasonable care in the production, marketing, delivery and sale of their products. These Defendants were required to use reasonable care to avoid injuring Plaintiffs.

340. As discussed above, the Manufacturing Defendants were required by law to take various actions that they failed to perform, and in failing to do what is required by law, acted negligently.

341. A defendant is liable for negligent misrepresentation where it, in the course of its business, profession or employment, or in any other transaction in which it has a pecuniary interest, supplies false information for the guidance of others in their business transactions and the defendant fails to exercise reasonable care or competence in obtaining or communicating the false information

[250] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), http://www.wvgazettemail.com/news-health/20161217/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses.

[251] *AmerisourceBergen*, *supra* n.249.

at issue. A defendant is liable for the pecuniary loss caused to others by their justifiable reliance upon the information.

342. In the course of their businesses, each Manufacturing Defendant made, and caused to be made, affirmatively false statements about opioids, including, but not limited to, statements concerning the unlikeliness of addiction to prescription opioids and their efficacy for the treatment of chronic pain. Each Manufacturing Defendant failed to exercise reasonable care and competence in communicating the false information. Plaintiffs, Plaintiffs' agents, Plaintiffs' members, the public, and persons on whom Plaintiffs and their agents justifiably relied, relied on the false information the Manufacturing Defendants provided.

343. Each Manufacturing Defendant wrongfully concealed the falsity of its statements, the truth about which Plaintiffs, Plaintiffs' agents, Plaintiffs' members, the public, and persons on whom Plaintiffs and their agents justifiably relied, despite exercising due diligence, did not discover until recently. Further, each Manufacturing Defendant's dissemination of false statements demonstrated a conscious disregard for the rights and safety of other persons that had a great probability of causing substantial harm.

344. The Manufacturing Defendants should have foreseen under the circumstances that the likely result of an act or failure to act would cause injury.

345. As a direct and proximate result of the Manufacturing Defendants' affirmatively false statements, Plaintiffs suffered economic loss, including, but not limited to, the payment of additional wages, salaries and other forms of compensation; expenditures for medical care or treatment, rehabilitation services or other care, treatment, services, products, or accommodations; and other expenditures incurred as a result of the Manufacturing Defendants' negligent misrepresentations.

SECOND CAUSE OF ACTION

Negligence
(Against the Distributor Defendants)

346. Plaintiffs incorporate by reference herein all of the allegations set forth above.

347. The Distributor Defendants have a duty to Plaintiffs to provide a reasonable standard of care in the sale and distribution of opioids. The Distributor Defendants must also comply with the statutory requirements of the CSA, 21 U.S.C. §§801-971, and its implementing laws and regulations. The CSA requires that distributors of controlled substances "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. §1301.74(b). "Suspicious orders" include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency. Distributor Defendants are required to report suspicious orders to the DEA. *Id.*

348. Plaintiffs and Plaintiffs' agents are intended beneficiaries of the protections of the federal laws and regulations referenced in the preceding paragraph by either express or implied provisions of those laws and regulations.

349. Plaintiffs' injuries are a type of harm that the federal laws and regulations referenced in the preceding paragraphs are intended to prevent.

350. The Distributor Defendants breached their duty to Plaintiffs to conduct their business with the reasonable standard of care that is clearly prescribed by federal laws and regulations. The Distributor Defendants breached that duty by distributing and furnishing quantities of opioids that were plainly suspicious and in excess of the quantity of opioids that could have possibly been intended solely for legitimate medical purposes.

351. The Distributor Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct. The Distributor Defendants were negligent in failing to disclose to the DEA and others, suspicious and excessive orders for

opioids in violation of the CSA and regulations interpreting it and, therefore, failed to meet their duties as registered distributors of controlled substances.

352. The trust placed in the Distributor Defendants by Plaintiffs creates a duty on behalf of the Distributor Defendants to prevent diversion of the medications it supplies to illegal purposes.

353. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to Plaintiff and its members, including epidemic levels of addiction and the diversion of opioids for illegitimate purposes.

354. Each of the Distributor Defendants sold opioids with the knowledge that the purchased opioids were likely being used for non-medical purposes and/or posed an inherent danger to patients who were using opioids for chronic pain.

355. As a proximate result of the failure to report and/or continual fulfillment of suspicious and excessive orders of opioids, the Distributor Defendants have caused Plaintiffs to incur excessive costs related to responding to the opioid crisis.

THIRD CAUSE OF ACTION

Common Law Fraud
(Against the Manufacturing Defendants)

356. Plaintiffs incorporate by reference herein all of the allegations set forth above.

357. Manufacturing Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements and intentionally and unlawfully omitting and/or concealing information that made statements Defendants did make knowingly false.

358. Specifically, the Manufacturing Defendants' deceptions during the relevant period include, but are not limited to:

(a) Manufacturing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addition, were overblown;

(b) Manufacturing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

(c) Manufacturing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with ***more*** opioids;

(d) Manufacturing Defendants' misrepresentations that screening tools effectively prevent addiction;

(e) Manufacturing Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;

(f) Manufacturing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

(g) Manufacturing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;

(h) Manufacturing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

(i) Purdue and Endo's misrepresentations that abuse-deterrent opioids reduce tampering and abuse;

(j) Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;

(k) Purdue's misrepresentations that it cooperates with, and supports, efforts to prevent opioid abuse and diversion;

(l) Insys' misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

(m) Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

(n) Insys' misrepresentations to third-party payors to secure approval for coverage;

(o) Insys' use of speakers bureaus to disguise kickbacks to prescribers; and

(p) Manufacturing Defendants' use of front groups to misrepresent that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

359. By engaging in the acts and practices alleged herein, Manufacturing Defendants omitted material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

(a) opioids are highly addictive and may result in overdose or death;

(b) no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

(c) high-dose opioids subject the user to greater risks of addiction, other injury, or death;

(d) the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

(e) claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

(f) Purdue's 12-hour Oxycontin fails to last a full 12 hours in many patients;

(g) Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

(h) Manufacturing Defendants failed to report suspicious prescribers and orders;

(i) Insys' use of kickback and insurance fraud schemes; and

(j) Manufacturing Defendants' failure to disclose their financial ties to and role in connection with KOLs and front groups.

360. As alleged herein, Manufacturing Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations and did so with the intent of misleading Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs or their agents relied.

361. These false representations and concealments were reasonably calculated to, made with the intent to, and did in fact deceive Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied.

362. Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied, justifiably relied on Manufacturing Defendants' representations and/or concealments, both directly and indirectly. Plaintiffs' injuries were proximately caused by this reliance.

FOURTH CAUSE OF ACTION

Unjust Enrichment
(Against All Defendants)

363. Plaintiffs incorporate by reference herein all of the allegations set forth above.

364. To prevail on a claim of unjust enrichment, a plaintiff must show that: (a) it conferred a benefit on a defendant; (b) the defendant had knowledge of the benefit; and (c) the defendant retained the benefit under circumstances when it was unjust to do so without payment to the plaintiffs.

365. Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied conferred a benefit directly on each Manufacturing Defendant and each Distributor Defendant by purchasing opioids manufactured by the former and distributed by the latter.

366. Plaintiffs were not in express contractual privity with any Manufacturing Defendant or Distributor Defendant.

367. Each Manufacturing Defendant and Distributor Defendant was aware of this benefit, in that each was aware of payments made by Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied for the purchase of opioids.

368. Further, each Manufacturing Defendant and Distributor Defendant retained the benefits – *i.e.*, the payments for opioids purchased therefrom – when it was unjust to do so, as the provision of opioids to Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied caused cataclysmic harm to Plaintiffs, Plaintiffs' communities, and the public. All Defendants retained the money they received from Plaintiffs, Plaintiffs' agents, Plaintiffs' communities, the public, and persons on whom Plaintiffs and their agents relied, when in justice and in equity that money belongs to them, and it would be unjust to allow Defendants to retain that benefit. Defendants' revenues were made, in part, at the expense of Plaintiffs.

369. In exchange for the opioid purchases, and at the time Plaintiffs and their members made these payments, Plaintiffs and their members expected that Defendants had provided all of the

necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

370. As an expected and intended result of their own conscious wrongdoing, Defendants caused the unjustness of the benefit they knowingly received and have profited thereby. They benefited from opioid purchases that Plaintiffs and their members made as a result of Defendants' conduct, as set forth in this Complaint, including Defendants' false marketing and failure to report suspicious sales.

371. It would be inequitable under these circumstances for the Defendants to retain this benefit without paying Plaintiffs for its value. Plaintiffs seek recovery of the benefit they conferred upon Defendants and by which Defendants were enriched as a result of their inequitable conduct.

FIFTH CAUSE OF ACTION

Violation of Ohio Corrupt Practices Act
(Ohio Revised Code, §§ 2923.31, et seq.)
(Against All Defendants)

372. Plaintiffs incorporate by reference herein all of the paragraphs set forth above.

373. At all relevant times, Defendants have been "persons" under Ohio Revised Code §2923.31(G) (because they are corporations);

374. The Ohio Corrupt Practices Act ("OCPA") makes it unlawful for any person "to conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt." Ohio Revised Code §2923.32(A)(1).

375. The OCPA, among other provisions, makes it unlawful for any person to "conspir[e] to violate" the provisions of the OCPA. Ohio Revised Code §2923.32(B)(1).

376. As alleged herein, at all relevant times, Defendants moved aggressively to both increase the size of the opioid sales market and then capture a large portion of that market. In so doing, the Manufacturing Defendants launched an aggressive nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids as being: (a) rarely, if

ever, addictive; (b) safe and effective for the treatment of chronic long-term pain; (c) abuse resistant or deterrent; or (d) safe and effective for other types of pain for which the drugs were not approved. All Defendants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids. In particular, Defendants, along with other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (the "Opioid Fraud Enterprise"), whose purpose was to deceive opioid prescribers, the public and regulators into believing that opioids were safe and effective for the treatment of long-term chronic pain and presented minimal risk of addiction and/or that Defendants were in compliance with their state and federal reporting obligations. In doing so, Defendants sought to maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for long-term, chronic and other types of pain. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants were able to extract billions of dollars of revenue. As explained in detail below, Defendants' years-long misconduct violated Ohio Revised Code §2923.31 et seq.

a. The Opioid Fraud Enterprise

377. At all relevant times, Defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of Ohio Revised Code §2923.31(C) because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Fraud Enterprise: (a) had an existence separate and distinct from each of its component entities; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; and (c) was an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturing Defendants, the Wholesaler Defendants, pharmacies, employees and agents of the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

378. Within the Opioid Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The Opioid Fraud Enterprise used this common communication network for the purpose of deceptively marketing, selling and distributing opioids to the general public. When their products, sales, distributions and failure to report suspicious sales were contested by other parties, the enterprise members took action to hide the scheme to continue its existence.

379. The participants in the Opioid Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and the continuing coordination of activities. Through the enterprise, Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues and market share, and minimizing losses. Each member of the Opioid Fraud Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers and fail to report suspicious sales.

380. The Opioid Fraud Enterprise engaged in, and continues to engage in, the deceptive marketing of opioids as non-addictive, as safe and effective for chronic long-term pain and for uses which have not been FDA-approved, and the failure to report suspicious sales. The Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids. To fulfill this purpose, the enterprise has advocated for, and caused the over-prescription and over-distribution of, opioids by marketing, promoting, advertising and selling opioids throughout the country and across state boundaries and by failing to report suspicious sales. Their receipt of monies from such activities consequentially affected interstate and foreign commerce. The enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under Ohio Revised Code §2923.31(I)(1).

381. The Opioid Fraud Enterprise functioned by marketing, selling and distributing opioids to states, counties, other municipalities, doctors, healthcare organizations, pharmacies and the consuming public, while failing to report suspicious sales. However, Defendants as co-conspirators, through their illegal enterprise, engaged in a pattern of racketeering activity, which involves a fraudulent scheme to increase revenue for Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through the deceptive marketing and sale of opioids and the failure to report suspicious sales.

382. Defendants participated in the operation and management of the Opioid Fraud Enterprise by directing its affairs, as described herein. While Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

383. Each of the members of the Opioid Fraud Enterprise furthered the ends of the enterprise, through the acts and omissions pled above and herein.

384. Each of the Manufacturing Defendants relentlessly promoted opioids as having little to no risk of addiction, as being safe and effective for the treatment of long-term chronic pain and/or other uses for which the drugs were not approved. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through and in collaboration with the pain foundations - a formidable partnership that marketed to hundreds of thousands of prescribers across the country. The relationship was strengthened, in part, by individuals, including physicians, that held different leadership roles at different times across the various entities participating in the enterprise over the years.

385. On numerous occasions, the Manufacturing Defendants funded the pain foundations' marketing efforts. The Manufacturing Defendants specifically chose to partner with the pain

foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third-party sources.

386. Furthermore, all Defendants knowingly failed to design and operate a system to disclose suspicious orders of controlled substances and failed to notify the appropriate Drug Enforcement Administration field division offices in their areas of suspicious orders, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

387. The members of the Opioid Fraud Enterprise worked together to further the enterprise by and among the following manner and means:

(a) jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;

(b) concealing the addictive qualities of the opioids from prescribers and the public;

(c) misleading the public about the addictive quality and safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling and/or distributing opioids;

(f) collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective; and/or

(g) failing to report suspicious sales as required by the CSA.

388. To achieve their common goals, Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein.

Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids.

389. The foregoing allegations support that Defendants were part of an association of entities that shared a common purpose, had relationships across the various members of the enterprise and collaborated to further the goals of the enterprise for a continuous period of time. The Manufacturing Defendants knowingly and intentionally engaged in deceptive marketing practices, and incentivized pain foundations, marketing firms and physicians to do so as well. Defendants knowingly and intentionally failed to report suspicious orders as required by state and federal law and inundated the market with opioids.

b. Mail and Wire Fraud

390. To carry out and attempt to carry out the scheme to defraud, Defendants, each of whom is a person associated in fact with the enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through a pattern of racketeering activity within the meaning of Ohio Revised Code §2923.31(I)(1), and which employed the use of mail and wire fraud.

391. Specifically, Defendants have committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of Ohio Revised Code §2923.31(I)(1)), within the past four years. The multiple acts of racketeering activity which Defendants committed, or aided and abetted in the commission of, were related to each other and also posed a threat of continued racketeering activity. They therefore constitute "racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels and employees of the enterprise. Defendants participated in the scheme to defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign commerce.

392. In devising and executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers and the public to obtain money from Plaintiffs by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

393. Defendants' predicate acts of racketeering, Ohio Revised Code §2923.31(I)(1), include, but are not limited to:

(a) Mail Fraud: Defendants violated Ohio Revised Code §2923.32 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: Defendants violated Ohio Revised Code §2923.32 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

394. Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials; the filling of suspicious orders; and the misleading of regulators and the public as to Defendants' compliance with their state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled and regulators would have not been misled but for Defendants' illegal scheme, including, but not limited to:

(a) the FSMB's publication of opioid prescribing guidelines entitled, "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

(b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) failing to report suspicious orders as required by state and federal law;

(h) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(i) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(j) documents to process and receive payment for opioids, including invoices and receipts;

(k) payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

(l) deposits of proceeds; and

(m) other documents and things, including electronic communications.

395. Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, the Manufacturing Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

396. Defendants also communicated by U.S. mail, by interstate facsimile and by interstate electronic mail with various affiliates, regional offices, divisions, distributors, regulators and other third-party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive prescribers, consumers and regulators, oversupply the market and fail to report suspicious sales.

397. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities are concealed from Plaintiffs and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the enterprise's activities made the unlawful tactics discussed herein even more deceptive and harmful.

398. The foregoing allegations support that the Manufacturing Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets, and all Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

c. Conspiracy Allegations

399. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. Defendants conspired to violate Ohio Revised Code §2923.31(I) as described herein.

400. Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third-party entities and individuals not named as Defendants in this Complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share and/or minimize losses for Defendants and their other collaborators throughout the illegal scheme and common course of

conduct. In order to achieve this goal, Defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

401. Indeed, for the conspiracy to succeed, each of the Defendants had to agree to deceptively market, sell and/or distribute opioids while failing to report suspicious sales. The unanimity of the Manufacturing Defendants' marketing tactics and all Defendants' failure to report suspicious sales gave credence to their misleading statements and omissions to prescribers, consumers and regulators, and directly caused opioids to inundate the country and damage Plaintiffs.

402. Defendants knew and intended that government regulators, prescribers, consumers and others would rely on the collective material misrepresentations and omissions made by them and the other enterprise members about opioids and suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by Plaintiffs and the public.

403. The Manufacturing Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

404. Defendants also knew that by failing to report suspicious sales, they would significantly increase their sales and profits.

405. The foregoing illustrates Defendants' liability under Ohio Revised Code §2923.31, *et seq.*, by engaging in their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

d. Effect on Plaintiffs

406. Plaintiffs' own experiences regarding opioids illustrate these national trends. For example, Plaintiffs have purchased (directly or indirectly), paid for and/or provided reimbursement for opioids intended for consumption by its members, retirees and their families.

407. As described herein, Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for Defendants, at the expense of Plaintiffs. The predicate acts were committed or caused to be committed by Defendants through their participation in the enterprise and in furtherance of their fraudulent scheme, and were interrelated in that they involved obtaining funds from Plaintiffs.

408. As fully alleged herein, Plaintiffs relied upon representations and omissions that were made or caused by Defendants.

409. Plaintiffs suffered injuries proximately caused by Defendants' racketeering activity. But for Defendants' misstatements and omissions and the scheme employed by the Opioid Fraud Enterprise, Plaintiffs would not be bearing the costs of their current opioid epidemic.

410. By reason of, and as a result of, the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, Plaintiffs have been injured in their business and property in multiple ways, including, but not limited to:

(a) payments for emergency department visits for opioid misuse, addiction and/or overdose have increased;

(b) payments for emergency department visits for infections related to opioid misuse, addiction, and/or overdose have increased;

(c) payments for hospitalizations related to the misuse, addiction and/or overdose of opioids have increased;

(d) payments for medicines to treat HIV, hepatitis C and other issues related to the opioid misuse, addiction and/or overdose have increased; and

(e) payments for opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) have increased.

411. Defendants' violations of Ohio Revised Code §2923.31 *et seq*. have directly and proximately caused injuries and damages to Plaintiffs, who are entitled to bring this action for three times their actual damages, as well as sanctions, injunctive/equitable relief, costs and reasonable attorneys' fees pursuant to Ohio Revised Code §2923.32(B).

SIXTH CAUSE OF ACTION

Violation of Racketeer Influenced and Corrupt Organizations Act (18 U.S.C. §1962(c)-(d)) (Against All Defendants)

412. Plaintiffs incorporate by reference herein all of the paragraphs set forth above.

413. At all relevant times, Defendants have been "persons" under 18 U.S.C. §1961(3) because they are capable of holding, and do hold, a "legal or beneficial interest in property."

414. RICO makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

415. RICO, among other provisions, makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

416. As alleged herein, at all relevant times, Defendants moved aggressively to both increase the size of the opioid sales market and then capture a large portion of that market. In so doing, the Manufacturing Defendants launched an aggressive nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain; (c) abuse resistant or deterrent; or (d) safe and effective for other types of pain for which the drugs were not approved. All Defendants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids. In particular, Defendants, along with other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, the Opioid Fraud Enterprise, whose purpose was to deceive opioid prescribers, the public and regulators into believing that opioids were safe and effective for the treatment of long-term chronic pain and presented minimal risk of addiction and/or that Defendants were in compliance with their state and federal reporting obligations. In doing so, Defendants sought to maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for long-term, chronic and other types of pain. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants were able to extract billions of dollars of revenue. As explained in detail below, Defendants' years-long misconduct violated 18 U.S.C. §1962(c)-(d).

a. The Opioid Fraud Enterprise

417. At all relevant times, Defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of 18 U.S.C. §1961(4), because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Fraud Enterprise: (a) had an existence separate and distinct from each of its component entities; (b) was separate and distinct from the

pattern of racketeering in which Defendants engaged; and (c) was an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturing Defendants, the Wholesaler Defendants, pharmacies, employees and agents of the FSMB, APF, AAPM, APS and APA, as well as other entities and individuals, including physicians.

418. Within the Opioid Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The Opioid Fraud Enterprise used this common communication network for the purpose of deceptively marketing, selling and distributing opioids to the general public. When their products, sales, distributions and failure to report suspicious sales were contested by other parties, the enterprise members took action to hide the scheme to continue its existence.

419. The participants in the Opioid Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and the continuing coordination of activities. Through the enterprise, Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues and market share, and minimizing losses. Each member of the Opioid Fraud Enterprise shared in the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers and fail to report suspicious sales.

420. The Opioid Fraud Enterprise engaged in, and continues to engage in, the deceptive marketing of opioids as non-addictive, as safe and effective for chronic long-term pain and for uses which have not been FDA-approved, and the failure to report suspicious sales. The Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids. To fulfill this purpose, the enterprise has advocated for, and caused the over-prescription and over-distribution of, opioids by marketing, promoting, advertising and selling opioids throughout the

country and across state boundaries and by failing to report suspicious sales. Their receipt of monies from such activities consequentially affected interstate and foreign commerce. The enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. §1961(5).

421. The Opioid Fraud Enterprise functioned by marketing, selling and distributing opioids to states, counties, other municipalities, doctors, healthcare organizations, pharmacies and the consuming public, while failing to report suspicious sales. However, Defendants, as co-conspirators, through their illegal enterprise, engaged in a pattern of racketeering activity, which involves a fraudulent scheme to increase revenue for Defendants and the other entities and individuals associated-in-fact with the enterprise's activities through the deceptive marketing and sale of opioids and the failure to report suspicious sales.

422. Defendants participated in the operation and management of the Opioid Fraud Enterprise by directing its affairs, as described herein. While Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements and financial statements.

423. Each of the members of the Opioid Fraud Enterprise furthered the ends of the enterprise, through the acts and omissions pled above and herein.

424. Each of the Manufacturing Defendants relentlessly promoted opioids as having little to no risk of addiction, as being safe and effective for the treatment of long-term chronic pain and/or other uses for which the drugs were not approved. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through, and in collaboration with, the pain foundations – a formidable partnership that marketed to hundreds of thousands of prescribers across the country. The relationship was strengthened, in part, by

individuals, including physicians, that held different leadership roles at different times across the various entities participating in the enterprise over the years.

425. On numerous occasions, the Manufacturing Defendants funded the pain foundations' marketing efforts. The Manufacturing Defendants specifically chose to partner with the pain foundations and individual physicians to publish and otherwise disseminate misleading, pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third-party sources.

426. Furthermore, all Defendants knowingly failed to design and operate a system to disclose suspicious orders of controlled substances and failed to notify the appropriate Drug Enforcement Administration field division offices in their areas of suspicious orders, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

427. The members of the Opioid Fraud Enterprise worked together to further the enterprise by and among the following manner and means:

(a) jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe and effective for the treatment of chronic, long-term pain;

(b) concealing the addictive qualities of the opioids from prescribers and the public;

(c) misleading the public about the addictive quality and safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling and/or distributing opioids;

(f) collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe or ineffective; and/or

(g) failing to report suspicious sales as required by the CSA.

428. To achieve their common goals, Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic pain as described herein. Defendants suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the addictive, unsafe and often ineffective nature of opioids.

429. The foregoing allegations support that Defendants were part of an association of entities that shared a common purpose, had relationships across the various members of the enterprise and collaborated to further the goals of the enterprise for a continuous period of time. The Manufacturing Defendants knowingly and intentionally engaged in deceptive marketing practices, and incentivized pain foundations, marketing firms and physicians to do so as well. Defendants knowingly and intentionally failed to report suspicious orders as required by state and federal law and inundated the market with opioids.

b. Mail and Wire Fraud

430. To carry out and attempt to carry out the scheme to defraud, Defendants, each of whom is a person associated in fact with the enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud).

431. Specifically, Defendants have committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343), within the past four years. The multiple acts of racketeering activity

which Defendants committed, or aided and abetted in the commission of, were related to each other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels and employees of the enterprise. Defendants participated in the scheme to defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign commerce.

432. In devising and executing the illegal scheme, Defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers and the public to obtain money from Plaintiffs by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

433. Defendants' predicate acts of racketeering, 18 U.S.C. §1961(1), include, but are not limited to:

(a) Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

434. Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials; the filling of suspicious

orders; and the misleading of regulators and the public as to Defendants' compliance with their state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled and regulators would have not been misled but for Defendants' illegal scheme, including, but not limited to:

(a) the FSMB's publication of opioid prescribing guidelines entitled, "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

(b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) failing to report suspicious orders as required by state and federal law;

(h) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(i) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(j) documents to process and receive payment for opioids, including invoices and receipts;

(k) payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

(l) deposits of proceeds; and

(m) other documents and things, including electronic communications.

435. Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, the Manufacturing Defendants made misrepresentations about opioids on their websites, YouTube and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

436. Defendants also communicated by U.S. mail, by interstate facsimile and by interstate electronic mail with various affiliates, regional offices, divisions, distributors, regulators and other third-party entities in furtherance of the scheme. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive prescribers, consumers and regulators, oversupply the market and fail to report suspicious sales.

437. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities are concealed from Plaintiffs and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the enterprise's activities made the unlawful tactics discussed herein even more deceptive and harmful.

438. The foregoing allegations support that the Manufacturing Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets, and all Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

c. Conspiracy Allegations

439. Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d), Defendants conspired to violate 18 U.S.C. §1962(c), as described herein.

440. Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third-party entities and individuals not named as Defendants in this Complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share and/or minimize losses for Defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, Defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

441. Indeed, for the conspiracy to succeed, each of the Defendants had to agree to deceptively market, sell and/or distribute opioids while failing to report suspicious sales. The unanimity of the Manufacturing Defendants' marketing tactics and all Defendants' failure to report suspicious sales gave credence to their misleading statements and omissions to prescribers, consumers and regulators, and directly caused opioids to inundate the country and damage Plaintiffs.

442. Defendants knew and intended that government regulators, prescribers, consumers and others would rely on the collective material misrepresentations and omissions made by them and the other enterprise members about opioids and suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by Plaintiffs and the public.

443. The Manufacturing Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

444. Defendants also knew that by failing to report suspicious sales, they would significantly increase their sales and profits.

445. The foregoing illustrates Defendants' liability under 18 U.S.C. §1962(d), by engaging in their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

d. Effect on Plaintiffs

446. Plaintiffs' own experiences regarding opioids illustrate these national trends. For example, Plaintiffs have purchased (directly or indirectly), paid for and/or provided reimbursement for opioids intended for consumption by its members, retirees and their families.

447. As described herein, Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for Defendants, at the expense of Plaintiffs. The predicate acts were committed or caused to be committed by Defendants through their participation in the enterprise and in furtherance of their fraudulent scheme, and were interrelated in that they involved obtaining funds from Plaintiffs.

448. As fully alleged herein, Plaintiffs relied upon representations and omissions that were made or caused by Defendants.

449. Plaintiffs suffered injuries proximately caused by Defendants' racketeering activity. But for Defendants' misstatements and omissions and the scheme employed by the Opioid Fraud Enterprise, Plaintiffs would not be bearing the costs of their current opioid epidemic.

450. By reason of, and as a result of, the conduct of each of the Defendants, and in particular, their pattern of racketeering activity, Plaintiffs have been injured in their business and property in multiple ways, including, but not limited to:

(a) payments for hospital and/or urgent care emergency department visits for opioid misuse, addiction, and/or overdose have increased;

(b) payments for emergency department visits for infections related to opioid misuse, addiction, and/or overdose have increased;

(c) payments for hospitalizations related to the misuse, addiction and/or overdose of opioids have increased;

(d) payments for medicines to treat HIV, hepatitis C and other issues related to the opioid misuse, addiction and/or overdose have increased; and

(e) payments for opioid overdose reversal medication such as Naloxone Hydrochloride (Narcan) have increased.

451. Defendants' violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused injuries and damages to Plaintiffs, who are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees pursuant to 18 U.S.C. §1964(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court grant the following relief:

A. Enjoin the Manufacturing Defendants from violating federal law by making any further false or misleading statements or omissions related to opioids;

C. Enjoin the Manufacturing Defendants and Wholesaler Defendants from failing to report suspicious orders as required by the federal CSA,

D. Order Defendants to pay costs, losses and damages for injuries sustained by Plaintiffs as a proximate result of the Manufacturing Defendants' and Wholesaler Defendants' unlawful conduct as set forth herein, including restitution, civil penalties, disgorgement of unjust enrichment, exemplary damages, treble damages where applicable and attorneys' fees and costs; and

E. Grant any such further relief as this Court deems appropriate.

JURY DEMAND

Plaintiffs respectfully demand a trial by jury.

DATED: April 13, 2018

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